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Alternative Formulations to Reduce CFC (Chlorofluorocarbons) Use in U.S. Exempted and Excluded Aerosol Products

Radian Corp., Austin, TX

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SECTION 1

INTRODUCTION

HISTORICAL PERSPECTIVE

The use of chlorofluorocarbons (CFCs) in specific categories of aerosol propellant use considered "nonessential" was banned in the U.S. by regulations promulgated in 1978 (1). An aerosol was defined as a package comprising a self-pressurized, non-returnable container constructed of metal, glass, or plastic that contains a fluid product and that is fitted with a valve for expelling the product as a spray, liquid, gas, foam, powder, or paste. The banned CFC propellants included the fully-halogenated types: CFC-11, CFC-12, CFC-113, CFC-114, and CFC-115.

In view of the recent renewed interest in reducing worldwide production and consumption of CFCs and other chemicals implicated in the depletion of the Earth's stratospheric ozone layer, the U.S. Environmental Protection Agency (EPA) undertook this study of currently exempted and excluded CFC aerosol applications and their alternatives.

The EPA and the Food and Drug Administration (FDA) initiated and supervised the three-stage program from 1977 to 1978 to eliminate most uses of fully halogenated CFC propellants for aerosol propellant applications except for "essential uses." If the CFC in the product functioned as more than a propellant or dispersant, it was considered "the product" or "part of the product" and excluded. The agencies held the concepts of "product" and "propellant" to be mutually exclusive. Also, the EPA and FDA evaluated the need for certain "essential" aerosol propellants. These were products that, for reasons of safety, health, or national security, required a CFC propellant. The initial EPA evaluation resulted in a list of approximately 14 general applications considered exempt.

In the years following the transition, a few additional petitions for exemptions were tendered. Some were accepted. In addition, agency clarification of the exclusion of specific product types was requested. Some products were added to the exempt list as the result of these activities. Exemptions were applied to the product category, rather than to specific products or brand names.

This report identifies technically feasible methods for reducing CFCs in aerosol products without adverse effects on human life and health (inhalants, pharmaceutical tablet press lubricants), military preparedness (lubricants for electronic gear), and the economy (cleaners and chill-testers for computer equipment).

MONTREAL PROTOCOL REQUIREMENTS

The August 1988 EPA regulations (2) implement the Montreal Protocol (3). The regulatory mechanism to implement the Protocol is different from the 1978 aerosol propellant ban. Rather than develop regulations specific to each industry application (such as aerosol production), the entire supply of fully-halogenated chlorofluorocarbons will be reduced.

The Montreal Protocol of 1987 and the corresponding EPA Final Rule to implement the Protocol require the following reductions in calculated levels of controlled CFCs:

- Beginning July 1, 1989, a freeze at 1986 consumption and production levels of CFC-11, -12, -113, -114, and -115 on the basis of their relative ozone depletion weights;
- Beginning mid-1993, a reduction of these CFCs to 80% of 1986 levels; and
- Beginning mid-1998, a reduction of these CFCs to 50% of 1986 levels.

In May 1989, delegates of the nations party to the Protocol met in Helsinki and agreed on a five-point declaration to strengthen the Protocol. The five points are as follows:

- Phase out consumption and production of ozone-depleting CFCs "not later than the year 2000."
- As soon as feasible, phase out halons and control and reduce other ozone-depleting substances that contribute significantly to ozone depletion.
- Accelerate development of environmentally acceptable alternative substituting chemicals, products, and technologies.
- Help developing countries by providing information, training, and possibly funding to facilitate adoption of acceptable alternatives.
- Urge all states that have not already done so to join the Protocol.

OBJECTIVES AND ORGANIZATION OF THE REPORT

The purpose of the present report is 1) after reviewing the application, availability, and cost-effectiveness of CFC alternatives, to determine if suitable non-CFC alternatives or alternatives with lower CFC content can be substituted for those aerosol products in the U.S. that still use CFCs, and 2) to determine the steps necessary to convert to the best alternatives.

Section 2 of this report describes exempted and excluded CFC aerosol applications in the U.S., as well as those applications not covered by the regulation. Section 3 discusses the current U.S. consumption of exempted, excluded, and nonregulated CFC products. Suggested alternative aerosol formulations are discussed in Section 4, and the economics of their development and application are explored in Section 5.

Section 6 presents the conclusions of the study and discusses the most promising alternative formulations for CFC aerosols remaining in use in the U.S. Based on suggested scenarios for introducing the alternatives, the following reductions in CFC aerosol usage in the U.S. are judged possible (see Sections 4 and 6):

CFC Products	Present Consumption	1990 Usage Scenario One	1990 Usage Scenario Two	1995 Usage Scenario Three	2000 Usage Scenario Four
Mold Releases	1.50	1.50	1.11	0.00	0.00
Lubricants- (electric/electronic)	1.90	1.90	1.10	0.00	0.00
Lubricants-Tablets	1.00	1.00	0.68	0.00	0.00
Solvents- (electric/electronic)	6.00	6.00	4.20	0.00	0.00
MDID (Metered-Dose Inhalant Drugs)	3.90	4.00	4.00	5.25	0.50
Contraceptives	0.10	0.10	0.10	0.00	0.00
Solvents-Medical	0.60	0.60	0.46	0.00	0.00
ALL OTHERS	10.50	0.00	0.00	0.00	0.00
	25.50	15.00	11.65	5.25	0.50

Units: MM lbs/yr.*

In addition, CFC control measures may need to be examined for certain self-pressurized products not covered in this report. For example, in 1977, EPA granted an exemption to flying insect sprays used in tobacco barns. The exemption was not limited by container size. Depending on the barn size and layout, one insecticide averaging 35% Vapona (2,2-dichlorovinyl dimethyl phosphate and related compounds) and 65% CFC-12 was used in sizes ranging from 12 Av.oz. to 25 lbs. For this product, considering density, the "aerosol" containers are limited to net weights of approximately 24 Av.oz. (1 lb. 8 oz.) or less.

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*Readers more familiar with metric units may use the conversion factors in Appendix C.

SECTION 2

CFC AEROSOL APPLICATIONS EXEMPTED IN THE U.S.

Table 1 lists CFC aerosol applications exempted from EPA's and FDA's 1978 regulations.

EPA's final rule-making excluded aerosols containing propellant only, i.e., aerosols that do not propel another material. In such instances the propellant becomes the product. Also, when the CFC is an active ingredient, the aerosol product assumes a nonregulated status. The concepts of "product, active ingredient, and concentrate" and "propellant" are held to be mutually exclusive, and regulations only deal with aerosol propellants. Table 2 lists the CFC aerosol applications that are excluded from the regulation.

The rationale applied in 1978 and 1979 by EPA and the FDA when considering proposed exemptions included the following:

- The need for a nonflammable product;
- The five years often taken by the Drug Division of the FDA to approve an Amended New Drug Application (applies to bronchodilators and other inhalants, and vaginal contraceptive foams for human use);
- Required solvency and purity profiles, e.g., CFC-113;
- Doctrine of equivalency--that highly similar products cannot reasonably be treated differently;

TABLE 1. SPECIFIC EXEMPTED AEROSOL PROPELLANT APPLICATIONS - 1978

1. Release agents for molds used to produce plastic and elastomeric materials;

2. Lubricants for rotary-type press-punches for the production of pharmaceutical tablets;

3. Lubricants, cleaner-solvents, dusters or coatings for industrial/institutional applications to electronic or electrical equipment;

4. Mercaptan stench warning devices for mines;

5. Other warning devices, such as intruder alarms, boat horns, bicycle horns, etc.;

6. Flying insect pesticides for use in commercial food handling areas, except when applied by total release or metered valve aerosol devices;

7. Propellants for flying insect pesticides for the fumigation of aircraft;

8. Flying insect spray for tobacco barns;

9. Metered dose inhalant drugs, as follows:

    -- Steroid drugs for humans, (oral and nasal)
    -- Ergotamine tartrate drugs, and
    -- Adrenergic bronchodilator drugs (oral);

10. Contraceptive vaginal foams for human use;

11. Aerosols for the maintenance and operation of aircraft;

12. Aerosols necessary for the military preparedness of the United States of America;

13. Diamond grit sprays; and

14. CFC-115 ($CClF_2$-CF_3) for the aeration of puffed food products.

TABLE 2. EXCLUDED CFC AEROSOL APPLICATIONS

CFC as Active or Sole Ingredient

1. CFC-12 used as a polyurethane blowing agent (insulation foams);
2. CFC-12 and CFC-114 mixtures used in tire inflators;
3. Certain specialty foams, whips, and puffs
4. Medical solvents such as silicone-based bandage adhesive (CFC-113) and bandage adhesive remover (CFC-113, with 5% CO_2);
5. CFC-12 and CFC-114 refrigeration and air-conditioning system refill units[a];
6. Drain openers;
7. Microscope slide cleaners;
8. Computer cleaners and dusters (equivalent to number 3 in Table 1);
9. Boat horns;
10. Halon fire extinguishers (the types containing 95% Halon-1211 and 5% CO_2 may not be excluded);
11. Intruder alarm sonic devices for homes and cars; and
12. Skin chillers--for medical purposes.

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[a] The aerosol industry recognizes these products as "aerosols" in surveys and close involvement with the marketing firms.

- Limited availability of substitute propellants or products;
- Stratospheric ozone impact, e.g., production tonnage per year; and
- Life-saving potential of the proposed exempted product, e.g., medical, military, flammable gas alarm systems, etc.

RATIONALE FOR EXEMPTED USES OF CFC AEROSOLS

This section will specifically examine the rationale for exempting certain aerosol products from the 1978 ban on CFC use. Where possible, products in similar groupings will be treated as a unit.

Release Agents (For molds to produce plastics and elastomers for medical applications. Also, for mold chambers in punch presses used to produce pharmaceutical pills and tablets.)

CFC-11 and CFC-12 are used, sometimes with CFC-113, in an industrial environment. The solvent propellant system must be extremely pure to prevent product contamination. The system must also be compatible with the item being formed to minimize such effects as colorant bleed, distortion, and filler micro-crystallization. Since the solvent/propellant system may be used repeatedly, and usually in a controlled environment with negative-pressure settings, minimum flammability, preferably nonflammability, is an important attribute. The solvent must be volatile so that all but ppb traces are gone by the time the product is packaged and possibly radioisotopically sterilized. CFC-11 and CFC-113 provide this volatility, while also modifying the particle size distribution of the spray to achieve optimum surface coating efficacy.

When the application was made for CFC-11, CFC-12, and CFC-113 to be exempted from the regulation, the only available nonflammable propellant was HCFC-22. The possible nonflammable chlorinated solvent alternatives were methylene chloride and 1,1,1-trichloroethane (4). Both contain considerable amounts of mixed inhibitors (free-radical chain stoppers), such as 1,4-dioxane and nitromethane. The effect of these high-solvent substances on molded medical products was sometimes deleterious; they sometimes volatilized from them with difficulty, and the contamination effects of the various inhibitors would have caused the FDA to require a penetrating evaluation of product purity and toxicology.

Lubricants, Cleaner-Solvents, Dusters and/or Coatings for Electronics

Extremely pure CFC-12 and CFC-113 are used to make sprays of varying particle size distribution for treating finished electric or electronic circuit boards, tuners, computer lay-outs, and similar "hi-tech" articles. Where lubricant application or solvent-based cleaning is required, a mixture of about 25% CFC-12 and 75% CFC-113 is the choice. Coating sprays (other than lubricants--such as anti-static) may use 30-35% CFC-12; the remainder is CFC-113. Duster sprays often use 100% CFC-12. Vapor-phase defluxers use various blends of CFC-12/113, depending on the specific application.

CFC-113 is preferred because of its extreme purity when purchased in grades specific for the purpose and because of its compatibility with materials of construction. It can effectively remove oils, solder by-products, greases, inorganic dusts, and other detritus without adversely affecting elastomers, plastics, and metals. Any more critical treatment of the subject would have to consider individual applications.

The firms seeking an exemption claimed that there was no substitute chemical with the extreme purity, nonflammability, materials compatibility, and the volatility of CFC-113. One manufacturer of personal computer boards cited a room where 10 to 15 operators sprayed residue materials from finished boards at the rate of two to five boards per minute. Besides leaving traces of petroleum oils on the boards, the use of hydrocarbon gases, such as isobutane, would have caused a fire hazard in an area where testing equipment was needed that could not be purchased in explosion-proof designs.

Mercaptan (Thiol) Stench-Type Warning Devices

Typically, these devices are used in mine tunnels to warn of the buildup of seeping methane and/or carbon monoxide flammable gases. The devices are operated by a small, portable sniffer-tester that continuously monitors the air and detects flammable gases by the differentiating action of a Wheatstone Bridge circuit. The stench device is preferred to a siren, since some miners may be operating air hammers or drills and may also have hearing deficiencies because of their long exposure to the 110-decibel noise of these tools.

The typical aerosol container, equipped with a piston-operated actuational device, contains an ethyl mercaptan (ethylthiol) stenching agent in a mixture such as one of the following:

3%	Ethyl Mercaptan
17%	1,1,1-Trichloroethane (4)
80%	CFC-12
	or
2%	Ethyl Mercaptan
98%	CFC-12

Mining companies seeking the exemption reported the life-saving attribute of the product, also pointing out that a nonflammable composition was necessary, since 1) the entire can was discharged quite rapidly and 2) there was already a buildup of flammable gases; deliberately releasing more would serve to exacerbate an already hazardous situation.

Other Warning Devices

Other self-pressurized warning devices include home and car intruder alarms, boat horns, etc. They generally consist of 100% CFC-12. Since large quantities of gas are released at one time--often the entire can contents--under a variety of closed or open environmental conditions, the use of a flammable propellant seemed unwise. (At the time the exemption was sought, no toxicologically safe, liquid nonflammable alternative propellant had been identified.)

The firms seeking an exemption pointed out that products designed for the preservation of life and property should not, of themselves, be hazardous to use. Small (though potentially dangerous) amounts were released each time, and there were no available substitutes. Also, the production volume was fairly low.

Flying Insect Pesticides (For use in commercial food-handling areas, except for total-release and meter-sprays; also for killing insects in and on aircraft and in tobacco warehouses.)

The products for commercial food-handling areas have the following typical formula:

2%	Pyrethrins & Piperonyl Butoxide Toxicants
18%	Petroleum Distillates (Food Grade)
36%	CFC-11
44%	CFC-12

Minor amounts of methylene chloride and/or iso-butane have also been included in some products as less costly alternatives.

Two other approaches were proposed but rejected.

The petitioning marketers were not interested in providing total release or meterspray products to these food-handling establishments and suggested that EPA exclude those forms from the exemption they were seeking.

Aircraft fumigation is used to prevent the entry of unwanted insects into the United States. In some instances, the products also contain a disinfectant ingredient to reduce surface-contact bacteria, molds, mildew, yeasts, rickettsia, virus, and other micro-flora.

Regulations vary among countries, but many require fumigation with nonflammable formulations in aerosol dispensers, both at their home ports of entry and in aircraft of their register. In the U.S., the American Pilots Association has established a code, accepted by the carriers, that only nonflammable aerosols shall be used for fumigation. This is also a regulation of the Civil Aeronautics Board.

Aircraft are not made explosion-proof, and the possibility exists that excess, localized spraying in a sensitive area by a poorly informed person could lead to a fire, although not to an explosion (9.6 g of hydrocarbon propellant is capable of bringing 55 U.S. Gallons of air to the flammable range).

In the petition for exempting these pesticides from the regulation, the option of a water-based product was considered, but it was rejected for three reasons: 1) it still contained 30 to 32% hydrocarbon propellant, although it was technically nonflammable by standard test methods then in use; 2) the heavier particle size caused fall-out to affect the passengers and polished surfaces; and 3) because of the fall-out, the odor of the toxicants was more persistent than with true space sprays.

The exemption allowed for tobacco barns and warehouses has apparently been liberalized to cover tobacco warehouses and food warehouses if they contain tobacco products. Nevertheless, this is a de minimus application, and some users have converted, because of economic incentives.

The petition claimed that tobacco leaves, dusts, and granules are both costly and very flammable; thus, flammable sprays should not be used in buildings that contain these materials. Tobacco in the dried state is also highly absorbent and would pick up a certain amount of the emulsifiers, inhibitors, and other ingredients of water-based flying insect sprays, adulterating the tobacco.

Metered-Dose Inhalant Drugs (Steroids, ergotamine tartrate and adrenergic bronchodilator types.)

This category represents about 4% of the U.S. domestic aerosol unit volume, although the products are very small in size. The usual range is from about 0.5 Av.oz. (14 g or 10 mL) to about 0.75 Av.oz. (21 g or 15 mL). The CFC content is 87 to 96 percent. In general, 70 to 80% of the CFC content is CFC-12. The other CFCs are CFC-11 and CFC-114. A typical formulation follows:

1.5%	Solid Drug (Generally powdered to 2-10 microns)
1.5%	Excipients
12.0%	CFC-11
10.0%	CFC-114
75.0%	CFC-12

The less common solution types use about 10% anhydrous ethanol as a co-solvent; about 85% or more CFC-12 is used in such products to achieve the desired break-up of the spray. Unless the particles are within 0.5 to 10 microns in size, they will not penetrate beyond the extrusile cilial area and up to the alveolar tubes and sacs where pulmonary abnormalities may exist. For example, Al-buterol, used in about half of all these products, requires deep penetration to be effective.

To reduce thermally sensitive powdered drugs into the 2- to 10-micron particle size distribution, they may be mixed with an appropriate non-solvent liquid of high volatility into a slurry and then ground or milled. As frictional heat is generated, it is instantly dissipated into solvent warming or volatilization. None of the drug houses has explosion-proof equipment in their FDA-approved processing facilities--nor do they have the flammable gas detection devices; blow-out walls; electroprotective systems; multi-stage, high-intensity ventilation; and other systems that would be needed if the slurry liquid were highly flammable [such as n-pentane (B.P. = 98°F) or iso-pentane (B.P. = 86°F)]. Consequently, the slurrying agent must be nonflammable and available at a high level of purity. CFC-11 (B.P. - 74°F) fulfills this requirement.

In some preliminary studies of a CFC-11/hydrocarbon system, the hydrocarbon propellant was found to have a bad (stinging, oily) taste, especially if the product was designed for oral entry, instead of nasal inhalation.

In 1977 and 1978, the pharmaceutical houses advised the FDA (Drug Division) of the above facts, stating that no alternative slurrying agent was available for CFC-11, and that non-CFC propellants were inimical to product organoleptics and performance. They also reported that, even if nonflammable and otherwise acceptable alternatives were available, they would require three to five years of developmental work, followed by a five-year study by the FDA before marketing approval could be obtained. Without a continuing supply of CFCs, these life-saving and remedial drugs would no longer be available.

Contraceptive Vaginal Foams

These drugs were marketed after extensive testing by pharmaceutical firms and by the FDA (Drug Division). Testing of an alternative formula would have to proceed almost from the beginning and would take an estimated seven years to complete. The FDA favored the use of CFC-12/114 propellant blend over the A-46 (iso-butane/propane) blend; the New Drug Amendment (NDA) granted in the late 1960s was based only on the CFC formula option.

Vaginal foams are not a life-saving product. The exemption was granted because, while alternative propellants were available, they could not be used until many years of retesting had been conducted. Also, the market for the products was rather small, and only about 6.4 g of CFCs were used per average 3 Av.oz. dispenser. Had the usage level been higher, the FDA might have not granted the exemption, feeling that other routes to contraception were available.

Hair Restorers

During 1988, however, the FDA granted an NDA to the Upjohn Company for a hair restorer product. The marketer provided information to the agency on products using both CFC and A-46 (iso-butane/propane blend) propellant options. Despite the Montreal Protocol and heightened concerns about the stratospheric ozone layer, the FDA selected only the CFC option for marketing.

The product is a quick-breaking foam, is quite small in size (2 Av.oz.), and contains less than 10% CFC blend. Thus, it is extremely similar to the contraceptive vaginal foam in product/package characteristics. Ultimately, it could capture a substantial market.

Aerosols for Aircraft (Maintenance and Operation)

Little information is available on these aerosols. Along with the Flying Insect Fumigants discussed above, these aerosols include lubricants, cleaners, and other industrial items. Considerations such as safety, high value, and flammability potential--the largest aircraft can hold almost a tank truck-sized load of aviation fuel--have led the American Pilots Association (APA) and related organizations to recommend the restriction of service aerosols to nonflammable options.

Two nonflammable options for a lubricant aerosol are the following:

CFC Type:	2%	SAE 30 Motor Oil - Winterized
	5%	Modified Dimethylsiloxane (Silicone Oil)
	23%	1,1,1-Trichloroethane
	40%	CFC-11
	30%	CFC-12

Alternative:	2%	SAE 30 Motor Oil - Winterized
	5%	Modified Dimethylsiloxane (Silicone Oil)
	83%	1,1,1-Trichloroethane
	5%	Odorless Mineral Spirits (Flash Point 129°F (54°C) Set-A-Flash Closed Cup)
	5%	Carbon Dioxide

Following are two options for spray paints for touch-up and corrosion control:

CFC Type:	55%	Aerosol Paint Concentrate (Generally Acrylic)
	45%	CFC-12
Hydrocarbon: (flammable)	55%	Aerosol Paint Concentrate (Generally Acrylic)
	15%	Acetone or Methylene Chloride
	30%	Hydrocarbon Blend A-85 52% Propane and 48% Iso-butane

Although APA would not approve of the hydrocarbon version, the Factory Mutual Research & Engineering Company has shown that the two formulations are virtually indistinguishable in terms of intrinsic flammability.

Military Aerosols (For continuing military preparedness)

The U.S. Armed Services purchases about 1,000,000 pounds of CFC-12/CFC-11-propelled insecticides a year by contract. Most are Flying Insect Sprays for troops, but some are specialty items, such as Wasp and Hornet Sprays with CFC-113, designed to protect maintenance personnel working on power stations and utility lines. Significant numbers are exported to military bases overseas.

The Armed Forces also purchases various other aerosol products, and may at their option select CFC formulations, apparently without specific justification. The number of CFC aerosols is thought to be relatively low, and their use is restricted to military aircraft maintenance, computer de-dusting, metal flaw finding, magnetic tape sprays, and specialty lubrication.

Diamond Grit Sprays

Very little information could be found, except that the market is minuscule.

DuPont, Allied-Signal, and Racon had no record of selling CFCs for such an application. No one could imagine using such a product except for diamond "sand blasting" extremely hard metallic surfaces to micro-etch them.

CFC-115 For Puffed Food Product Aeration

DuPont, which is the only remaining domestic supplier of CFC-115 for this use, has not sold the product to a whipped cream manufacturer or food company in many years.

The original whipped creams consisted of water dispersions of either natural or synthetic whipped cream ingredients, pressurized with CO_2 and N_2O (or the White's Mixture of these food grade propellants). For economic reasons, formulations were then limited to synthetic whipped creams with nitrous oxide (N_2O) propellant. The limited solubility of the N_2O gas forced marketers to fill cans to only about 55 to 60% by volume and to use maximum pressures of N_2O. Otherwise, the product became "soupy" near the end of the can.

From 1968 through 1971, when food aerosol dispersions increased dramatically in the aerosol industry, DuPont developed their Freon (Food Propellant) C-318 (chemically, perfluorocyclobutane), which could be added to the N_2O at the rate of 3 to 6 g per 9 Av.oz. can to give a much more uniform whip throughout the life of the dispenser. It also allowed 2 to 3 additional

Av.oz. to be included in the can, at the penalty of slight "soupiness" near the end.

The problem was that the C-318 cost $7.50/lb. A typical use of 4.5 g per can increased the factory cost by $0.20 per can, and even more if extra product were added to the can. Since the new cans looked the same size as the original ones, consumers bought the lower-priced original formulas, and C-318 production ended.

DuPont then obtained FDA approval for CFC-115, which was well known but never used for aerosols because it cost $1.50/lb. CFC-115 was tried in several products during the 1977 to 1978 petition period. Marketers based their petitions on the argument that their sales would seriously decrease without the "bail-out" attributes of CFC-115, that the propellant had only one chlorine atom and should pose a reduced threat to the ozone layer, and that only about 5 grams were needed per can. At the time, roughly 38,000,000 units of whipped creams were sold a year, or 190 metric tonnes per year of CFC-115, if every marketer used the propellant.

The marketer team also advised the FDA that no other propellants were practical. Freon C-318 was unavailable except in pilot quantities, the Food Grade hydrocarbons gave the product an oily, slightly biting off-taste, and nitrogen was too insoluble.

After the petition was granted, with limits on product type and usage levels, the price of CFC-115 increased moderately. Marketers began to look at another option. The American Can Company had recently introduced their Rim Vent Release (RVR) mechanism on the top double seam of three-piece aerosol cans, which opened up a number of apertures if the can became dangerously overpressurized. The Department of Transportation (DOT) normally limits aerosol pressures to 180 psig at 130°F if the cans were ordered with RVR fixtures. The product was nonflammable and not otherwise hazardous if it did escape the container. Ultimately, DOT granted an industry petition, which allowed marketers to insert 17% more N_2O gas into the product. This reduced the "soupiness" problem and slowly led to the complete elimination of CFC-115 in these products.

At least two firms are testing CFC-115 in anhydrous "edible whip" products of the general type recently patented by the Ring Chemical Company in New Jersey. It gives them a better taste than the 3% Propane mentioned in the patent. One firm is considering use of CFC-115 until HFC-134a (CH_2F-CF_3) comes onto the market and can perhaps be approved as a Food Grade propellant. Propane may also be used, as a last resort.

RATIONALE FOR EXCLUDED USES OF CFC AEROSOLS

Drain Openers

The aerosol drain opener was developed by Glamorene, Inc. (Secaucus, NJ) about 1972. The actuator consisted of a 2 and 11/16 inch plastic hemisphere with the exit hole at the apex. The unit was upended over the drain hole of a clogged sink and pressed downward, opening a valve to allow CFC-12 gas into the drain pipe, which normally acted to blow the clog out of the gooseneck. Problems were encountered when drain liquids were blown out of the other drain in double sink installations. Many bathroom sinks had side orifices to prevent overflow, and these sometimes acted as pressure outlets as well. Pipe connectors sometimes separated.

The product consisted of 100% CFC-12. It did not meet criteria such as life-safety, high value in use, no available alternative, and minimum consumption of CFC gas-liquids.

Eventually the high cost, excessively large can size, infrequency of use, and the many problems caused consumers to discontinue purchasing it. The franchise was sold to another marketer, and sales eventually ceased.

Microscope Slide Cleaners

A blend of about 75% ultrapure CFC-113 and 25% CFC-12 is used to flush across the microscope lens while it is still in the microscope holder. Loose dry specimens, specimens under oil, dusts, and other objects are conveniently flushed off, after which any remaining CFC-113 quickly evaporates. This is a great time-saver for many institutional facilities where repetitive assays or examinations are required.

Chewing Gum Removers

Flattened lumps of chewing gum are difficult to remove from carpeting and other floor coverings, but the task is greatly facilitated by using a chewing gum freezant spray of CFC-12, which acts to draw down the gum temperature to about -60°F (-51°C) or lower by successive evaporations off the surface. The "pancake" then becomes very brittle, able to be fractured or broken up with a sharp blow. The pieces can then be removed while still frozen.

This aerosol product was launched after the 1978 restrictions or bans. It is used mostly in institutions and accounts for about 350,000 lbs. of CFC-12 per year. As of July 1989, at least two major CFC suppliers refused to sell any more CFC-12 for this application.

Boat Horns

The dispensers and associated horn devices are made by specialty firms. Arguments for continuing the use of 100% CFC-12 in such packages are 1) the sense of weightiness (15 Av.oz. per can) that connotes a good product; 2) the nonflammability of the product (sometimes large amounts are released at one time); and 3) marketers usually manufacture their own products in facilities that are not explosion proof and where they could not safely produce the less costly hydrocarbon propellant alternative products.

Most of these marketer/fillers produce a considerable variety of aerosol products, all of them pressurized with CFC propellants or containing 100% CFCs. By September 1989, several manufacturers had switched to using HCFC-22 in heavy walled (nonaerosol) cylinders.

Halon-type Fire Extinguishers

The portable dispenser area of this market is divided into two segments: the aerosol type and the cylinder type. The aerosol is limited to two sizes: the twin-pack of two 4 Av.oz. cans in a belt-carrier canister, with a common actuator, and the 12 to 15 Av.oz. pack, in a red enameled, Mylar-labeled aluminum container, coded and approved for use by Factory Mutual R&E Laboratories, Underwriters Laboratories, or one of the three other product testing laboratories recognized as reliable. The aerosols nearly always use a blend of 20 to 25% Halon 1301 ($CBrF_3$) and 80 to 75% Halon 1211 ($CBrClF_2$). The objective is to obtain a pressure that will allow the aerosol to pass specific fire tests, yet that will not exceed the "DOT Specification 2Q" specification of 180 psig (maximum) at 130°F (54°C), and that is considered "self propelling" (not requiring a pressure gauge).

The cylinder or tank portion of this market is several times larger. Several firms sell six or more product sizes, offering the aerosol size for car or boat and the larger sizes for home use.

The Halon is considered "the product" since it provides the fire extinguishing action. It is considered a life-safety product. Unfortunately, bromine is also 3 to 10 times more able to destroy ozone than chlorine (Cl), depending on the Halon molecule it is in.

Intruder Alarm Devices (For cars, trucks, and homes)

These products are high-intensity (100 to 110 decibel) horns triggered electrically by various sensing devices. Large amounts of gas are discharged in each alarm cycle to achieve a persistent sonic effect. Because of this, nonflammable gas is preferred, especially for indoor locations. The cost premium for the CFCs (over the hydrocarbon alternative) represents a small increment of the overall device.

Skin Chillers (For medical purposes)

These aerosols are typically packaged in aluminum cans, filled to 8 to 10 Av.oz. with CFC-12 or a blend of CFC-12 and CFC-114. They are used by medical personnel to perform minor topical operations, such as the removal of a splinter, a wart, a non-melanomic skin cancer, and so forth, by deadening the afflicted area. It avoids the use of injected Novocaine and similar anesthetics. Chillers have also been used to shrink fingers and facilitate the removal of rings that have become too tight.

Using flammable gas alternatives in a hospital or clinical setting would not be approved by the medical profession. Products known to have such propellants would not be used, despite their lower cost. Dimethylether is the most effective propellant for this application, but it is somewhat flammable.

Polyurethane Blowing Agent

A typical formula for this type of aerosol product is as follows:

45%	Toluene di-isocyanate
20%	Polyethylene Glycol (PEG) Derivatives
32%	CFC-12
3%	Dimethylether (DME)

The dimethylether is present only to bind up residual moisture that can otherwise act to catalyze the reaction between the pre-polymer and the PEG derivatives. The fact that it is a propellant is incidental. The CFC-12 is used to ensure production of an essentially nonflammable, stable foam. In cursory studies with foams containing hydrocarbon propellant blowing agents, ignition was instant and was followed by very rapid burning--with the production of modest amounts of cyanides, cyanogen, and related toxic substances.

Tire Inflators

Approximately 75% of the usual tire inflator consists of a water dispersion of resin and ethylene glycol, and a trace of amphoteric surfactant; 25% is a hydrocarbon blend A-46 (iso-butane and propane).

When a tire is reinflated with these products, the gas space will then contain about 35 to 65% by volume of flammable hydrocarbon gas. This is well above the Upper Explosive Limit (UEL) of about 8.6 v% for propane/butanes and air, but in subsequent activities (some directed on the label) this volume may be diluted with air into the flammable range of 1.9 to 8.6 v%. Tires in this state have been subjected to removal, to adjacent rim welding repairs, and to other incidents that resulted in internal combustion, fragmentation of the tire, and severe, often fatal, injuries to the operator.

In 1986 one such marketer met with representatives of EPA and the Consumer Products Safety Commission (CPSC) in Washington, DC, proposing that the agencies permit the substitution of the hydrocarbon propellant by 55% CFC-12/114 (40:60). The agencies confirmed that they had the right to do this because the CFCs would constitute a part of the product and because they had inflating action. Within two months the revised product was on the market.

Lawsuits increased, and during late 1988 another marketer developed a CFC-based tire inflator formula, but before going to market, the marketers estimated that for every million pounds they purchased 18 skin cancers and 0.8 deaths would occur annually. The firm did not market the product.

The CFC product is technically inferior and more costly than the standard hydrocarbon types; therefore, it has only been marketed by one firm.

Foams, Whips, and Puffs

From 1981 to 1986 a few small specialty firms produced CFC products of these types. For example, a firm formulated and packed an ablative, very heavy foam using CFC-12/114 (40:60). Finger-rings containing gemstones could be partly embedded in this foam while the back-side was being welded during re-sizing operations by jewelers. The stones remained cool and did not become strained or cracked. The self-filler had no explosion-proof facilities (in his basement) and was concerned about the flammability of foams that carried hydrocarbon propellants.

No other evidence was found of CFCs currently being used in the U.S. in non-drug aerosol products of this type.

Medical Solvents (Bandage adhesive and adhesive remover)

Two firms purchase a concentrate from the Dow Corning Corporation that contains a silicone-based adhesive dispersed in CFC-113. Contract fillers pour the concentrate into cans, seal them, and pressurize the contents with carbon dioxide (CO_2).

Dow-Corning scientists say that alternatives to CFC-113 are uniformly unacceptable for the product. For example, the 7 to 8% of free-radical reaction inhibitors in 1,1,1-trichloroethane have unknown effects when brought into contact with open wounds.

The adhesive remover is required since the breathable silicone film may bond the innermost layer of cotton gauze bandage to the skin surface, preventing removal. Acetone, ethanol, and many other solvents are either ineffective or present toxicological problems. Thus, a self-pressurized adhesive remover is required. This consists of about 95.4% CFC-113 and 4.6% CO_2, in a fill weight of 6.0 Av.oz. per can.

SUMMARY

Approximately 28 individual product types and groups have been or are being produced in aerosol formulas that contain CFCs. This does not include CFC refrigeration/air conditioning refill products or ethylene oxide/CFC-12 gas sterilants, since these are not considered in aerosol exemptions or exclusions.

Background data on each product or product group is provided, including how the CFC component functions. Industry's interest in preserving the CFC ingredient(s) is explained. In the excluded categories, petitions were not required, but meetings were often held, nonetheless, to firmly establish that companies could go to market with CFC-based products falling into these categories. The primary reasons for requesting exempted status were the unavailability of substitutes, the long time delays while obtaining an amended NDA from the FDA, solvency and purity profiles (especially for CFC-113 uses), life-saving potential of the product, and regulations in hospitals, aircraft organizations, etc. against the use of flammable propellants in aerosols.

During the 1977 to 1978 transition period, no nonflammable liquid propellant alternatives to CFCs were toxicologically approved and commercially available for use. Today the situation has changed, with the clearance of HCFC-22 and certain blends of HCFC-22/142b, and the forthcoming availability of HFC-134a, HCFC-123, HCFC-141b, and HCFC-124.

As may be anticipated, some exempted or excluded aerosol products are no longer in use or have been replaced with ones that contain alternative propellants. However, inhalant and solvent type products are steadily growing in sales volume. See Section 3 for current U.S. consumption of CFCs and Section 4 for current and future alternative formulations for CFC aerosols. Section 5 presents a discussion of the costs of making these substitutions to alternative formulations.

SECTION 3

CURRENT U.S. CONSUMPTION OF CFCs

The main sources of information for this section are CFC manufacturers. Product formulas, average product net weights, and the differences in the sales volumes of similar products are estimated. The production volume of the aerosol industry in units per year for 1988 is determined from valve sales and from comparisons with the survey data published in 1987 by the Chemical Specialties Manufacturer's Association (CSMA) and the Can Maker's Institute (CMI). Categorical volumes are then derived by extending and augmenting the detailed CSMA data with specific data from industry contacts.

DISCUSSION OF THE DATA

Table 3 shows published data (5) illustrating an analysis of the major categories of the domestic CFC market. Table 4 shows a number of product categories of aerosols in which CFCs are still being used, or have been used since 1978. The U.S. CFC aerosol market in 1986 was 24,000,000 pounds. It grew by 3.9% in 1987 to 25,000,000 pounds. The CFC aerosol market in 1988 was projected to be about 25,500,000 pounds (as of October 1988).

The following paragraphs explain the information presented in Table 4.

Source of the Data

The source of the data obtained on CFC quantities and units filled is the aerosol industry, which defines aerosols in the same way as the U.S. Department of Transportation: pressure-resistant containers with a capacity of 50 cubic inches--819.35 mL or 27.71 fluid ounces. Larger containers, designated as cylinders or tanks, do not have the aerosol exemption, and (in general) are filled and marketed by firms other than those in the aerosol

TABLE 3. THE FULLY HALOGENATED U.S. CFC MARKET OF 1986 (CFC-11, -12, -113, -114, AND -115) (5)

PRODUCT TYPE	PERCENT	MM POUNDS
Refrigerants	40	290
Blowing Agents	28	200
Cleaning Agents	20	145
OTHERS	12	85
Liquid Freon Freezant Aerosols Etchants Sterilants		
	100	720

NOTES (6):

a. Liquid Freon Freezant (LFF) is 100% CFC-12.

b. Etchants are perfluoro- or highly fluorinated CFCs, mainly CFC-114, but including CFC-113, CFC-115, and FC-116. They are deliberately degraded by plasma arcs to produce HF for the etching of electronic parts.

c. The sterilants consist of the U.S. Patented, marginally non-flammable blend of 12% ethylene oxide (EO) and 88% CFC-12. Most is sold to medical facilities in large cylinders, but some is marketed in 12 Av.oz. aerosol containers.

d. The "Cleaning Agents" are 100% CFC-113.

e. mm = million

TABLE 4. AEROSOL MARKET PENETRATION OF CFC-CONTAINING PRODUCTS - 1988

PRODUCT DESCRIPTION	CFC CONSUMPTION (MM lbs)	AVERAGE CONTAINER SIZE (Fill wt - lbs)	PRODUCT VOLUME OF CFC VERSIONS (MM Units)	PRODUCT VOLUME FOR ALL VERSIONS (MM Units)	PERCENT OF PRODUCT CATEGORY USING CFCS
EXEMPTED PRODUCTS[a]					
Mold Release Agents	1.5	1.11	1.32	2.79	47.3
Lubricants for Electric/Electronic Equipment	1.9	0.76	2.32	12.8	18.1
Lubricants for Pharmaceutical Pill-making	1.0	0.86	1.93	1.93	100.0
Solvent-cleaners and De-dusters for Electric/Electronic Equip	6.0	0.51	10.9	19.8	55.1
Mercaptan Warnings	<0.1	0.95	<0.09	<0.09	100.0
Intruder Alarm Device	0.6	0.47	1.21	1.21	100.0
Flying Insect Sprays for Commercial Food Handling Areas	<0.1	0.76	<0.12	3.20	<3.7
Flying Insect Sprays for Aircraft	0.3	0.48	0.58	0.58	100.0

(Continued)

TABLE 4. (Continued)

PRODUCT DESCRIPTION	CFC CONSUMPTION (MM lbs)	AVERAGE CONTAINER SIZE (Fill wt - lbs)	PRODUCT VOLUME OF CFC VERSIONS (MM Units)	PRODUCT VOLUME FOR ALL VERSIONS (MM Units)	PERCENT OF PRODUCT CATEGORY USING CFCS
Flying Insect Sprays for Tobacco Barns	<0.05	0.76	<0.06	0.06	100.0
Metered Dose Inhalant Drugs: --Steroid Drugs --Ergotamine T. Drugs --Adr. Bronchodilator	3.9	0.033	107.0	107.0	100.0
Contraceptive Vaginal Foams for Human Uses	<0.1	0.16	<6.94	<6.94	100.0
Aircraft Maintenance and Operation Sprays	0.5	0.76	0.61	12.5	4.9
Military Aerosols	1.4	0.68	1.96	35.0	5.6
Diamond Grit Sprays	<0.05	0.76	<0.06	<0.06	100.0
CFC-115 for Aeration for Puffed Food Prods.	0	0	0	0	0

(Continued)

TABLE 4. (Continued)

	CFC CONSUMPTION	AVERAGE CONTAINER SIZE	PRODUCT VOLUME OF CFC VERSIONS	PRODUCT VOLUME FOR ALL VERSIONS	PERCENT OF PRODUCT CATEGORY
EXCLUDED PRODUCTS[b]					
Tire Inflators	1.0	0.93	1.65	17.02	9.7
Polyurethane Foam	3.1	1.01	9.17	9.17	100.0
Chewing Gum Removers	0.3	0.59	0.47	0.47	100.0
Drain Openers	<0.05	0.70	<0.07	<0.07	100.0
Chillers (Medical)	0.3	0.39	0.71	0.71	100.0
Boat Horns	1.9	0.77	2.28	2.28	100.0
Non-E/E De-dusters	0.4	0.43	0.86	0.86	100.0
Microscope Slide Cleaners & Related Products	<0.05	0.39	0.12	0.12	100.0
Solvents (Medical)	0.6	0.51	1.09	1.09	100.0
Contingency Products, Including Unauthorized Uses	0.2	0.50	0.41	--	--
	25.4				

(Continued)

TABLE 4. (Continued)

PRODUCT DESCRIPTION	CFC CONSUMPTION (MM lbs)	AVERAGE CONTAINER SIZE (Fill wt - lbs)	PRODUCT VOLUME OF CFC VERSIONS (MM Units)	PRODUCT VOLUME FOR ALL VERSIONS (MM Units)	PERCENT OF PRODUCT CATEGORY USING CFCS
OTHER PRODUCTS					
Aerosol Size Halon Fire Extinguishers 1301/1211 (Includes 30% Imported)	3.8	0.83	4.24	4.24	100.0
Refrigerator/Air-conditioner Refills (12 and 114)	67.7	0.96	70.5	70.5	100.0

[a] NOTE: These products are in the exempted category. The volume totals 17.5 MM lbs.

[b] NOTE: These products are the excluded and non-regulated types, in which CFCs form part or all of the concentrate; hence, they are not considered aerosol propellants. The volume, not including the "other" products (Halons and Ref/AC refills), is 8.0 MM lbs.

industry. The aerosol surveys by the Chemical Specialties Manufacturer's Association, Inc. (CSMA), the Can Maker's Institute (CMI), Precision Valve Corporation (PVC), et al. consider only those aerosols of capacities equal to or less than 50 cubic inches. Butane lighter fluids are not considered to be aerosols; however, CFC refill units within the size limitation are.

Although some exemptions have been granted for products marketed both as cylinders and as aerosols, as defined above, for the purposes of this report, the cut-off is the 50-cubic inch level; larger sizes are not considered in any detail.

Development of Numbers by Exact Product Type

When developing numbers for the column titled "Product Volume for All Versions (MM Units)," only units of the exact product type were considered. For example, the "Mold Release Agents" line refers to release agents for molds used in the production of plastic and elastomeric materials. Figures for mold release agents used for toy metal (tin-bismuth) soldiers, cookie forming, ice-cube-makers, some candlemaking, and other applications are not included, even though a small quantity of CFC is used in these areas.

Similarly, "Flying Insect Sprays for Aircraft Fumigation" were not compared with the 106,400,000-unit overall flying insect aerosol market.

Flying Insect Sprays

The use of flying insect sprays based on CFC formulations in commercial food preparation areas has dwindled to almost nothing. Previous formulas have been replaced by water-based, hydrocarbon-propelled formulas, supplemented by anhydrous, hydrocarbon-propelled types using time-metering canisters attached to walls or posts.

A major concern was restricting these sprays to food handling areas. Employees were apt to spray bathrooms, dressing areas, and other unauthorized locations. The higher cost was a further concern.

Although meter-sprayed aerosols are not exempted, the new formulas have been slow to replace the meter-spray CFC-12 types because the meter valve supplier could not readily produce a complex valve modification that would spray 40-45 mg shots of the low-density hydrocarbon formulas in place of the usual 100-110 mg bursts of the standard CFC compositions (7).

Aerosols for Military Use

The "Military Aerosols" category includes two sub-groups: the flying insect spray (CFC-type) and electric/electronic maintenance and testing products (also CFC-type). The U.S. government orders 1,500,000 10-Av.oz. units formulated with 2% Toxicants and 98% CFC-12/11 once a year. Depending on insect populations during any year, from about 1,250,000 to the full 1,500,000 units are released for shipment from the sole supplier.

These formulas account for up to 1,020,000 lbs of CFCs. In Table 4, the remaining 380,000 lbs of CFCs are for electric/electronic maintenance activities around sonar, radar, radio, servomotor, computer, airplane controls, and other sensitive, costly, or sparking types of equipment.

Metered Dose Inhalant Drugs

The three classes of meter-spray inhalant aerosols used for medical purposes can be defined as follows:

- Metered-dose steroid human drugs for oral inhalation;
- Metered-dose steroid human drugs for nasal inhalation; and
- Metered-dose adrenergic bronchodilator human drugs for oral inhalation.

Information from the Haskell Laboratories Division of DuPont shows the equivalence of nasally and orally inhaled drugs of the steroid types; they are generally identical except for the plastic nose or mouthpiece.

Table 4 of the present report only gives a total figure for all metered-dose inhalant drugs. The breakdown of these drugs is as follows:

Steroid drugs--oral	20 (% units)
Steroid drugs--nasal	10 "
Ergotamine Tartrate vasoconstrictor drugs	3 "
Bronchodilator drugs--oral	67 "

The Ergotamine Tartrate types represent less than one percent of CFCs used in this category. This inhalant is a cranial vasoconstrictor, used for migraine and prodrome control. Two new metered-dose ethical drug products, a hair restorer (quick-breaking foam) and a curative pulmonary spray for bronchial pneumonia--so far only FDA-approved for AIDS patients--are reported to contain CFC propellants. The volumes for these products are unavailable, since each is made by only one firm and the market results would be too revealing. The hair restorer was released in 1988 and the other was conditionally approved in early 1989.

Additional details on metered-dose CFC-containing drug aerosol products appear in Appendix A.

Conversion of Pounds of CFCs Consumed to Aerosol Units Sold

When calculating aerosol units offered for sale from pounds of CFCs consumed (and vice-versa) it is seen that:

- Aerosols are regulated as "delivering systems" for net weight purposes, and must therefore be filled to an average of 0.10 to 0.25 Av.oz. over labeled weight, according to size.

- An average of about 8% total propellant is lost during the handling and filling process. This includes leakages, machine discharges, and the 1.5 to 2.5% of all aerosol units lost through process leakage, bad quality, testing, samples, pilferage, etc.

- Not all CFC aerosols are 100% CFC. Examples of CFC percentage levels in other products are:

Flying Insect Killers (Military)	98%
Lubricants and Mold Releases	95%
Inhalants	94%
Contraceptive Foams	8%

Conversion equations then become:

$$\frac{\text{CFC Usage (lbs)}}{\text{Actual fill (lbs)} \times \text{CFC Loss Factor} \times \text{CFC Fraction}} = \text{Units}$$

U.S. MARKETERS AND FILLERS OF CFC PRODUCTS

A substantial number of marketers and contract fillers currently produce the estimated 5% of all aerosols that still contain CFC-type propellants. Some of these firms are listed in Table 5.

TABLE 5. MARKETERS AND FILLERS CURRENTLY PRODUCING CFC-TYPE AEROSOLS IN THE U.S.[a]

Tradenames	Company Name	City Address
Fluorosolv	Kem Manufacturing Corp.	Tucker, GA
Flux-Off	Chemtronics, Inc.	Hauppauge, NY
En-Rust, Cobra, Aeroduster	Miller-Stephansen Chemical Company	Danbury, CN
Aervoe	Aervoe-Pacific Company	San Leandro, CA
All Four, Fault Finder	Crown Industrial Products Company	Hebron, IL
AudioTex & Calectro	G.C. Electronics Division	Rockford, IL
Chargette	Airosol Company	Neodessa, KS
Cold Spray	Zee Medical Products Co.	Irvine, CA
Hollister	Hollister Medical Products	Chicago, IL
JC	Larson Laboratories, Inc.	Erie, PA
Contax & Grime-Solv	Stewart-Hall Chemical Corp.	Mt. Vernon, NY
Delfen Foam (Vaginal)	Johnson and Johnson, Inc.	Raritan, NJ
Exit (Chewing Gum Rem.)	Avmor, Limited	Montreal (Canada)
Drain Power (Obsolete?)	Airwick Industries, Inc.	Carlstadt, NJ
ReleasaGen (four items)	ReleasaGen Manufacturing Co.	Delano, MN
Minus 62 (Freezant)	Tech Spray, Inc.	Amarillo, TX
Lectro-Safe	DuBois Chemicals, Inc.	Cincinnati, OH
Koromex Foam (Vaginal)	Holland-Rantos Co., Inc.	Trenton, NJ
Lubri-Bond	Electrofilm, Inc.	Vanencia, CA
Mace (Several types)	Smith & Wesson Co.	Springfield, MA
Mace (Other types)	General Ordinance Equip. Co.	Springfield, MA
Mold-Ease & Solv-Clean	Chem-Pak, Inc	Winchester, WV
Quick Freeze	Sentry Chemical Company	Stone Mountain, GA
Freez-It, Lubrite, etc.	Workman Electronic Products	Sarasota, FL
Industrial Freezant	Rolmar: The Supply Corp.	Lake Geneva, WI
Freez'n Check & 70 PSI	ChemTronics, Inc.	Hauppauge, NY
Steel-One	Madison Bionics, Inc.	Franklin Park, IL
Seal Aid & Spra-Dri	Orb Industries, Inc.	Upland, PA
Zapper (Personal Protection)	Safety & Security Company	Harleysville, PA
(Contract Filler)	Aerosol Systems, Inc.	Macedonia, OH
(Contract Filler)	Chase Products, Inc.	Maywood, IL
Dri-Slide	Dri-Slide, Inc.	Freemont, MI
(Contract Filler)	Armstrong Laboratories, Inc.	West Roxbury, MA
Electro-Freez, Falcon, etc.	Falcon Engineering Co.	Mountainside, NJ
Flaw Finder	American Gas & Chemical Co.	Northvale, NJ
Benvenue	Benvenue Laboratories, Inc.	Bedford, OH
Globe Spray (For endoscopic work)	Globe Medical Instruments, Inc.	Clearwater, FL
Makiki, Voltex & Term-Out	Makiki Electronics Company	Hauula, Hawaii

[a] Inhalant drug producers are not listed.

SECTION 4

SUGGESTED ALTERNATIVE FORMULATIONS FOR EXEMPTED AND EXCLUDED CFC AEROSOLS

INTRODUCTION

The CFC propellants in exempted and excluded aerosols are currently preferred for a variety of reasons. Such reasons include their nonflammability, high purity, unique solvent characteristics (CFC-113 in particular), or the fact that they have been made an essential part of New Drug Amendments (NDAs) for pharmaceutical meter-spray aerosol products.

Other propellants or blends may exhibit some of these properties. Since 1983, a set of four alternatives to CFCs has been commercialized, and another set of four is expected to come onto the market in 1992 or 1993 if the results of toxicological testing programs continue to be favorable. The physical properties of the eight alternatives are summarized in Table 6. All the presently available alternative propellants are gases at room temperature. Boiling points are 14°F or lower; therefore, none can be considered a direct replacement for CFC-11 (B.P. = 73.3°F) or CFC-113 (B.P. = about 120°F), which are liquids at room temperatures.

Although HCFC-22 is nonflammable and is commercially available, teratogenic uncertainty has discouraged marketers of metered-dose pharmaceutical inhalant aerosol sprays. The extreme solvent activity of dimethyl ether is an additional concern for those firms marketing drug products in solid suspension forms because of Ostwald Ripening effects that change particle size distributions.

In this section, two or more formulation options will be presented for a number of products that currently use regulated CFCs. Some have a relatively greater potential for stratospheric ozone depletion than others. Although the

TABLE 6. CURRENT AND POSSIBLE FUTURE ALTERNATIVE AEROSOL PROPELLANTS

	Currently Available				Available in 1992 or 1993			
PRODUCT:	HCFC-22	Dimethyl-Ether	HFC-152a	HCFC-142b	HFC-134a	HCFC-141b	HCFC-123	HCFC-124
Formula	$CHClF_2$	$(CH_3)_2O$	CHF_2-CH_3	$CClF_2-CH_3$	CF_3-CH_2F	CH_3-CCl_2F	CF_3-CHCl_2	$CF_3-CHClF$
VP (psig) @ 70°F	121	63	63	29	81	<0	<0	46
VP (psig) @ 130°F	297	174	177	97	202e	17e	25e	125e
Boiling Point (°F)	-41	-13	-13	-14	-16	89.6	83.7	12
Flammability Range, % (LEL-UEL)	NF	3.3 - 18	4 - 17	7 - 15	NF	6 - 15	NF	NF
Solubility in H_2O, wt%	3	35	1.7	0.5	NA	NA	NA	NA

e=estimated

NA = Not available, but low

NF = Not flammable

aerosol industry has received sample amounts of most "future possible alternative propellants," product properties must be estimated when proposing the use of these materials in any future aerosol formulations.

DISCUSSION OF ALTERNATIVE CFC FORMULATIONS

This section will present alternatives to CFC aerosol formulations by 1) discussing the currently exempted and excluded products individually; 2) offering general comments; 3) suggesting alternative formulas; and 4) drawing conclusions.

Factors that were considered when developing the alternative formulations include the following:

- Production of sprays with desired particle size distribution;
- Control of flammability;
- Precautionary use of questionable solvents, such as methylene chloride;
- Minimum changes in anticipated use patterns;
- Maintenance of dispenser and organoleptic stabilities;
- Cost of alternative formulations;
- Availability of the alternative, including Toxic Substance Control Act (TSCA) considerations;
- Pressure limitations;
- Product utility or efficacy for intended uses;

- Toxicological factors; and

- Spray rate and use-up rate optimization.

Mold Release Agents

These products are currently formulated from an approximately 3 to 5% base of lecithin, functional silicone, or other material dissolved in a CFC-11/CFC-12 blend. Product purity, propellant volatility, and nonflammability are key properties. The plastics and elastomers being molded should not be contaminated with such unknown entities as solvents or inhibitors. The base should be delivered to the mold surface with as little loss (bounce) as possible. CFC-11 currently provides the desired high-transfer efficiency.

Two representative CFC-based formulas are as follows:

I.	3%	Lecithin (Soy Bean Source)
	57%	CFC-11
	40%	CFC-12
II.	5%	Silicone (Dimethacone -- 1000 centistokes)
	65%	CFC-11
	25%	CFC-12
	5%	Propane A-108

Both are intrinsically nonflammable.

When traces of inhibitors (such as nitromethane or 1,4-dioxane) are not a problem, an optional formulation such as the following may be suggested:

III.	3%	Lecithin (Soy Bean Source)
	27%	Methylene Chloride - Inhibited
	5%	Ethanol - Anhydrous (Liquid denaturants only)
	39%	HCFC-142b
	26%	HCFC-22

The inclusion of methylene chloride is based on studies by Dow Chemical Company, et.al. showing that the single positive mutagenicity study was (animal) species specific and that the compound does not affect humans. The total formulation would have a pressure of about 48 psig at 70°F (air-free basis). It would have a density of about 1.19 g/mL at 70°F, meaning that only about 80% of the present weight of these products could be placed in the filled can.

If methylene chloride is considered unacceptable from the standpoint of toxicology or solvency, it could be replaced by 1,1,1-trichloroethane - inhibited (4), as in the following formulation:

IV.

3%	Lecithin (Soy Bean Source)
37%	1,1,1-Trichloroethane - Inhibited
36%	HCFC-142b
24%	HCFC-22

This would bring approximately 3% of decomposition inhibitors (as free-radical chain breakers, such as nitromethane, etc.) into the formula, since they are necessary to counter the self-destruction of the 1,1,1-trichloroethane.

The boiling point of 1,1,1-trichloroethane (about 152°F) is high enough that small amounts could remain for a short time on the die surfaces, depending on conditions, and cause voids in the molded part.

The most costly formulation must await the availability of HCFC-123 or HCFC-141b. The formulation could be as follows:

V.

3%	Lecithin (Soy Bean Source)
65%	HCFC-123 (B.P. = 82°F)
32%	HCFC-22

If a preference develops for HCFC-141b (flammable) over HCFC-123 because of price or toxicology, a final formula option can be considered:

VI.

3%	Lecithin (Soy Bean Source)
14%	HCFC-123 (B.P. = 82°F)
50%	HCFC-141b (B.P. = 90°F)
33%	HCFC-22

Formulas V and VI would have pressures and liquid densities comparable to those of the present products. Solvency, for the bases, would be excellent. Formula VI could be checked for flammability, as should the possibility of replacing the 14% HCFC-123 with 14% additional HCFC-141b, should this be desired.

Lubricants for Electric and Electronic Equipment

Aerosol lubricants may assume numerous forms, according to the end use. For example, a lubricant for screen doors, sliding aluminum doors, door locks and hinges could consist of the following:

VII.	80%	Specialty Lubricant Blend
	15%	1,1,1-Trichloroethane - Inhibited (4)
	5%	Carbon Dioxide

This lubricant could also be dispensed through a capillary extension tube up to 8 inches long fitted into the actuator orifice.

Electrical applications, as for motors, transformers, switches, and relays, generally require a nonflammable product and a spray delivery. This is especially true of aerosols, where large-scale, spark-producing equipment, such as the commutator ring of a 250 HP motor or dynamo, must be lubricated. CFCs have been used in these lubricants to ensure that the combustibility of the specialty oil itself is suppressed. Some of these products are also used in rooms or areas where smoking and the use of flammable or combustible solvents are prohibited. The composition of one such product follows:

VIII.	5 - 15%	Specialty Lubricant Blend
	65 - 50%	CFC-11
	30 - 35%	CFC-12

The use of hydrocarbons or other flammable propellants is contraindicated for electrical equipment because sparks of sufficient energy (over 0.2 kilojoules) can ignite flammable-range mixtures of these gases and air, harming both operator and equipment. In some instances, spark streams or electrical resistance may act to strongly heat a surface, causing combustible solvents to heat up beyond their flash point, and flammable solvents to heat up beyond their auto-ignition point.

Finally, easily decomposed halogenated solvents may produce hydrogen chloride, phosgene, and other active gases that can act corrosively on hot contact points, resistors, etc. The CFCs (especially CFC-12 and CFC-114) are highly resistant to pyrolysis.

In the electronics area, sprays must be nonflammable because of equipment or environment restrictions; pyrolytic corrosion is also a concern. One of several products is formulated as follows:

IX.

5%	Specialty Lubricant Blend
65%	CFC-113
30%	CFC-12

The CFC-113 carries the lubricant to the surface to be treated, allowing a minimum amount to contaminate the air. At the same time it exerts a degreasing, flushing action, removing unwanted vapor fluxer residues and dusts.

Several alternatives to CFC products are available. First, when motors, computer boards, and similar items are not electrically connected, and unless the added solvency of 1,1,1-trichloroethane (4) is a problem, Formula VII can be used in conjunction with a meter-spray valve that will reduce the amount of lubricant sprayed out. For example, a 6 Av.oz. can be made to give about 1700 "shots" of about 100 mg each.

For greater uniformity of the spray pattern during package life, another formula could be considered:

X.

60%	Specialty Lubricant Blend
12%	1,1,1-Trichloroethane - Inhibited (4)
28%	HCFC-22

If the presence of 1,1,1-trichloroethane creates a problem, the following more costly meter-spray option should be useful in a "DOT Specification 2Q" aerosol can:

XI.	68%	Specialty Lubricant Blend
	32%	HCFC-22

Finally, if a product comparable to Formula IX is needed, a counterpart to CFC-113 will present the greatest challenge. The best candidate is the following:

XII.	5%	Specialty Lubricant Blend
	72%	HCFC-141B
	23%	HCFC-22

The structural similarities of HCFC-141b (CH_3-CCl_2F) and CFC-113 ($CClF_2$-CCl_2F) suggest they may possess a similar solvency potential. Formula XII is of marginally acceptable flammability. This can be corrected, if necessary, by using additional HCFC-22, or by using a meter-spray valve. In time, the replacement of HCFC-22 with HFC-134a could result in a lower pressure and a lower concentration of chlorine in Formula XII.

Lubricants for Pharmaceutical Pill and Tablet Manufacture

These products must be nonflammable and leave only a Food Grade [(Generally Recognized As Safe (GRAS)-listed] residue on surfaces contacted by the pharmaceutical item. Following is a typical formula:

XIII.	2.0%	Lecithin (Soy Bean Source)
	0.5%	Sorbitan Trioleate
	2.5%	Ethanol - Anhydrous (Pure Grain Spirits)
	70.0%	CFC-113 (Especially purified)
	25.0%	CFC-12

Since a high-purity, nonflammable, volatile liquid is required, which can currently only be met by CFC-113, a 32% immediate reduction (in ozone depletion potential) can be made by using the following formula:

XIV.	2.0%	Lecithin (Soy Bean Source)
	0.5%	Sorbitan Trioleate
	2.5%	Ethanol - Anhydrous
	65.0%	CFC-113
	10.0%	HCFC-142b
	20.0%	HCFC-22

If and when HCFC-123 becomes commercially available, the formulation could then be revised to the following:

XV.	2.0%	Lecithin (Soy Bean Source)
	0.5%	Sorbitan Trioleate
	2.5%	Ethanol - Anhydrous (Pure Grain Spirits)
	77.0%	HCFC-123
	18.0%	HCFC-22

If HCFC-123 does not become commercially available, the following alternative nonflammable formula can be offered:

XVI.	2.0%	Lecithin (Soy Bean Source)
	0.5%	Sorbitan Trioleate
	2.5%	Ethanol - Anhydrous (Pure Grain Spirits)
	55.0%	HCFC-141b
	30.0%	HCFC-124
	10.0%	HCFC-22

Solvent-Cleaners, Dusters, and Coatings for Electric/Electronic Equipment

The solvent-cleaners and dusters for delicate electric and electronic items consist almost uniformly of the following:

XVII.	75%	CFC-113
	25%	CFC-12

Except for the inclusion of approximately 1 to 3% active ingredients, various coating sprays are similarly formulated.

CFC-113 is unique because of its nonflammability, relative volatility, high purity, compatibility with materials of circuit-board and other constructions, and for its selective solvent action on greases, oils, and solder by-products. In some instances, combinations of other solvents may suffice, such as 1,1,1-trichloroethane, followed by deionized water and then heat lamps. However, the best immediate course of action may be to replace the CFC-12 (and perhaps a part of the CFC-113) with other propellants, as shown below:

XVIII.	82%	CFC-113
	18%	HCFC-22

or

XIX.	70%	CFC-113
	16%	HCFC-142b
	14%	HCFC-22

If HCFC-123 becomes commercially available, this nonflammable liquid could be formulated as follows:

XX.	83%	HCFC-123
	17%	HCFC-22

Alternatively, the following replacement formula can be offered:

XXI.	60%	HCFC-141b
	30%	HCFC-123
	10%	HCFC-22

A final alternative takes advantage of the high-pressure azeotrope of HCFC-22/Propane (68:32), which has a pressure of about 135 psig at 70°F and therefore cannot be added to aerosol cans except as individual ingredients. The blend is flammable, but it can be rendered nonflammable by the use of HCFC-123; for example:

XXII.	87.00%	HCFC-123
	4.16%	Propane A-108
	8.84%	HCFC-22

Metered-Dose Oral and Nasal Inhalation Pharmaceutical Products

This category now accounts for about 4 million pounds of CFCs a year in the U.S. (15% of all CFC aerosol uses) and includes approximately 70% of the 152 million CFC aerosol product units sold annually. The dollar value of these products is very high, allowing latitude in reformulating them with more costly propellants. The average canister holds 16.0 g, or about 0.56 Av.oz. The estimated formulas of five high-volume metered-dose inhalant drug (MDID) products are shown in Table 7.

The ultimate conversion of the various "metered-dose inhalant drugs" (MDIDs) to non-CFC formulations represents the greatest individual challenge of all aerosol changeovers. Industry contacts repeatedly assert that MDID is a life-preserver for thousands of dependent users.

Of the presently available "CFC alternative propellants" only HCFC-22 is nonflammable. The nonflammable attribute is highly desired because most MDID users are heavy smokers and may be holding cigarettes while using the product. (The importance of this aspect is arguable.) However, other problems with HCFC-22 are listed below:

a. Teratogenicity

- HCFC-22 inhaled at 50,000 ppm for 40 hours per week by pregnant rats in the middle trimester resulted in 0.15% anophthalmia and 0.05% cryptophthalmia; Imperial Chemical Industries, Ltd. (ICI) considers these findings to be statistically significant.

b. Other Toxicological Aspects

- Inhalation toxicology studies beyond those now completed would be required for industry approval. The FDA is satisfied with the present array of results.

TABLE 7. ESTIMATED FORMULAS OF FIVE MDID PRODUCTS (PERCENT)

Ingredients	Broncho-dilator	Broncho-dilator	Broncho-dilator	Steroid	Steroid
Drug	1.00	0.147	0.714	0.24	0.386
Sorbitan Trioleate	1.00	0.853	1.000	--	1.000
Ethanol - Absolute	--	--	--	1.00	--
CFC-11	20.00	15.000	24.571	--	20.000
CFC-12	78.00	69.000	49.144	98.76	58.614
CFC-114	--	15.000	24.571	--	20.000

- The drugs now used for adrenergic bronchodilator and corticosteroid therapy are themselves teratogenic to animals, and there is a concern that one teratogen (HCFC-22) could reinforce the teratogenic activity of another (the drugs). Thus, teratogenic testing of any proposed new-propellant products would be needed.

- The greater solvency--thus mucosal and tissue permeation--of HCFC-22 could cause a more concentrated drug tide to be carried through the pre-alveolar tubes, leading to possible toxicological and "toxic shock" effects.

c. Reduced Liquid-phase Density

- A predominantly HCFC-22 product would be about 10 to 15% lower in density than the usual MDID items; e.g., 1.2 g/mL, compared with 1.4 g/mL. This could cause faster settling of the solid drug in the powder dispersion formulas that make up about 90% of the industry sales volume.

- Since the meter-spray valve is volumetrically based, about 10 to 15% higher percent by weight levels of the drug and excipients would be required. Likewise, labeled net weight would have to be reduced or converted to labeled net volume.

d. Increased Product Pressure

- The pressure of HCFC-22 is 297 psig at 130°F; whereas, that of CFC-12 is 180 psig at 130°F. Under Title 49 of the Code of Federal Regulations (CFR), the Department of Transportation regulates the interstate shipment of most aerosols [Sections 173.306(a) and 173.1200(8)]. Most aerosols are not permitted to have pressures exceeding 180 psig at 130°F, and containers for these products are constructed accordingly. (Applies to containers larger than 118.2 mL capacity.)

- Unless the HCFC-22 pressure is significantly reduced by the use of suppressant type propellants (such as HCFC-142b), enhanced leakage rates and other deterrent factors might develop.

e. Increased Solvency

- HCFC-22 is a substantially better solvent than CFC-11, CFC-12 or CFC-114, and could dissolve or partly dissolve certain micronized microcrystalline drugs. In the latter case, unwanted crystal growth could occur as the larger crystals grow at the expense of the smaller ones. This could eventually reduce delivery of the product to the sub-cilial pulmonary regions or even cause meter-spray valve blockage.

f. Difficulties in Reformulation

- HCFC-22 has been reported by 3M (Riker Laboratory) and other drug houses to complicate product redevelopment.

A better approach might be formulas such as the following:

XXIII.

Drug	0.50%
Sorbitan Trioleate	1.00%
CFC-11	13.50%
HCFC-142b	51.00%
HCFC-22	34.00%

Pressure:	61 psig 70°F (air-free)
Flammability:	Nonflammable*
Density:	1.19 g/mL at 70°F

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*Both the slurrying liquid and the propellant blend are nonflammable in air.

or one based on HFC-134a as the main propellant, such as the following:

XXIV.		
	Drug	0.50%
	Sorbitan Trioleate	1.00%
	HCFC-141b	9.50%
	CFC-11	4.00%
	HFC-134a	75.00%
	HCFC-124	10.00%
	Est. Pressure:	70.5 psig at 70°F (air free)
	"	180 psig at 130°F (air free)
	Flammability	Nonflammable*
	Est. Density:	1.20 g/mL at 70°F

---

*Both the slurrying liquid and the propellant blend are nonflammable in air.

Following are several reasons to develop a formula based on HFC-134a as the main propellant:

a. HFC-134a looks extremely promising as a refrigeration/air conditioning fluid and aerosol propellant of exceptionally low toxicity. It also has no Cl or Br atoms, and therefore does not affect the stratospheric ozone layer.

b. HFC-134a may eventually be produced in numerous countries for refrigeration/air conditioning uses, so that worldwide availability should not be a problem.

c. The pressure of the system is comparable to the pressures of the current MDIDs; e.g., 70.5 psig at 70°F compares to 52 to 70.7 psig at 70°F (air free).

d. The solvent activity of HFC-134a is comparable to that of the CFC-12 now in use for MDIDs.

e. The density of Formula XXIV, while only about 85% that of the usual MDID should not pose significant formulation problems.

To maintain the same liquid volume (and canister size) and the same number of doses per package, the drug content would have to be increased by about 18% (w/w) for the same meter-spray dosage volume, and the net weight would have to be decreased by 15%.

Short of retaining current CFC formulas, there are no options for formulating MDID products at their current density levels of 1.34 to 1.40 g/mL at 70°F, except, possibly, for using Freon C-318 (perfluorocyclobutane: C_4F_8)--a low-pressure food-grade propellant commercialized during the 1970s but now discontinued because of its high cost, absence of market, and other factors. DuPont has been urged to re-examine the merits of this propellant, which has the desirable property of very low solvency.

f. The highest-pressure propellant is present in the largest percentage. This is equivalent to the present MDID formulas, where the percentage of CFC-12 present is from about 50 to 98. It allows the product to tolerate minor gas seepages (micro-leakage), which occur in all aerosols, but they have more significant effects on small dispensers with limited amounts of propellant.

Other important Formula XXIV considerations are presented below:

1. HCFC-141b (very slightly flammable; B.P. = 90°F) is very low in toxicity (in testing done to date) and is the primary slurrying agent.

   Because of the slight flammability, it is necessary to add not more than 4.00% CFC-11 (B.P. = 74°F) to produce a nonflammable solution. This approach has the following problems:

   - CFC-11 is a controlled stratospheric ozone depletion agent.

- It would complicate the NDA process if ultimate reformulation and/or different processing techniques become appropriate in the future. (Two NDA "openings" are more costly than one.)

Alternatives to using CFC-11 as part of the slurry follow:

- Use HCFC-123, which is nonflammable (Formula XXV).

- Use a blend of HCFC-123 and HCFC-141b that is shown to be nonflammable and contains the highest practical level of slightly flammable HCFC-141b to minimize pulmonary exposures to HCFC-123 (Formula XXVI).

- Use 100% slightly flammable HCFC-141b as the slurrying agent, taking necessary precautions to minimize the possibility of fire and/or explosion (Formula XXVII).

- Replace CFC-11 with CFC-113 (Formula XXVIII) for the following reasons:

    -- Its relative ozone-depletion potential is 80% that of CFC-11 (9).

    -- CFC-113 is less volatile than CFC-11 and can be handled in drums rather than cylinders.

    -- CFC-113's nonflammability in blends is similar to that of CFC-11, reflecting its lower volatility and higher molecular weight.

2. The "true propellant" portion is 75 parts of HFC-134a and 10 parts HCFC-124 (Formulas XXIV through XXVII). The latter is added to reduce the vapor pressure of the HFC-134a into the usual "DOT Specification 2Q" pressure range of less than 180 psig at 130°F. This means that the usual aluminum or stainless steel canisters will

suffice. However, for containers of less than 4 fluid ounces (118.2 mL), this is not a requirement.

Using straight HFC-134a is another option, if the extra pressure can be accommodated. The additional pressure would be about 5 psi at 70°F and 12 psi at 130°F. The consequences follow:

- A statistical reduction of HCFC ozone depletion by removing the HCFC-124 (Formula XXIX).

- Reduction in formula complexity by eliminating one ingredient (Formula XXX).

- Review of pressure-resistant qualities of the presently used aluminum canisters and vials. The supplier would have to guarantee their safe use for products with vapor pressures to about 192 psig (130°F) air free, and/or about 210 psig (130°F) if atmospherically clinched.

- Review of the Department of Transportation (DOT) position. Two pages from the present tariff containing regulations for compressed gases in dispensers of 7.5 cubic inches (4.0 fluid ounces, or 118.3 ml) or less appear in Appendix B of this report. Pressure limitations are not described. Products pressurized with propane (unsuppressed) are known to be sold in standard aluminum containers for nail guns and other uses. As currently produced, they have pressures of about 123 psig at 70°F and 278 psig at 130°F--with atmospheric crimps.

Table 8 summarizes the above detailed discussion of the various formulas, compares their properties, and gives preference ratings. (The pressure data in Table 8 are on an air-free basis. For 20"Hg° vacuum crimping, add 7 psi at 130°; for atmospheric crimping add 22 psi at 130°F.) The preference ratings in Table 8 assume that pharmaceutical firms and their fillers cannot reasonably handle the filling of slurries made with flammable dilutents having

TABLE 8. COMPARISON OF RECOMMENDED MDID FORMULAS

Formula Number:	XXIV.	XXV.	XXVI.	XXVII.	XXVIII.	XXIX.	XXX.
Ingredients (%)							
Drug	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Excipient(s)	1.0	1.0	1.0	1.0	1.0	1.0	1.0
HCFC-123		13.5	6.5				6.5
HCFC-141b	9.5		7.0	5.3	9.0	9.5	7.0
CFC-11	4.0			1.5		4.0	
CFC-113					4.5		
HFC-134a	75.0	75.0	75.0	66.7	75.0	85.0	85.0
HCFC-124	10.0	10.0	10.0	25.0	10.0		
Estimated Properties							
Pressure (70°F psig)	71	71	71	69	71	76	76
Pressure (130°F psig)	180	180	180	175	180	192	192
Density g/mL 70°	1.20	1.19	1.19	1.21	1.20	1.18	1.17
Slurry Flammable?	No	No	Border	Border	No	No	Border
Strat. O_3 Depletion Potential (CFC-11 = 1.00)	0.046	0.007	0.007	0.024	0.042	0.043	0.004

Preference Ratings:

Order of Preference (1 is Highest; 7 is Lowest)	If Toxicity Rating of HCFC-123 is Equal to or Better Than That of CFC-11	If Toxicity Rating of HCFC-123 is Significantly Worse Than That of CFC-11
1	XXV.	XXVII.
2	XXX.	XXIX.
3	XXVI.	XXIV.
4	XXVII.	XXX.
5	XXIX.	XXVI.
6	XXIV.	XXVIII.
7	XXVIII.	XXV.

flash points below room temperature. Otherwise, slurries of predominantly HCFC-141b would be recommended.

Finally, it is recommended that the MDID development chemists concentrate in two areas, as illustrated by the formulas shown in Table 9.

HCFC-124 is preferred over presently available HCFC-142b, because the latter is slightly flammable and the ability of HFC-134a to suppress this flammability is unknown.

When calculating the stratospheric ozone depletion values in Table 8, in the absence of complete data, the relative depletion potential of the various HCFC materials was calculated as 0.03 (based on CFC-11 = 1.00). The ozone depletion values of HCFC-22 and HCFC-142b are about 0.05 and 0.03, respectively. Using the 4.0 million-pound domestic use level (1988) of CFC propellants as a basis, Table 10 shows the calculated ozone depletion levels of the two MDID formulas ranked highest.

About 10% of the MDID aerosol volume consists of aerosols in which the drug item is in solution instead of in the usual microcrystalline suspension. In these formulas, if the drug can be dissolved in the concentrate (such as ethanol) and all halogenated ingredients added as a nonflammable propellant, then formulation possibilities become easier. The transition is suggested by the formulas shown in Table 11.

TABLE 9. FINAL RECOMMENDED MDID FORMULA PROTOTYPE

Formula No. Ingredients (%)	XXV. Assuming Toxicity Rating of HCFC-123 is as Good as or Better Than That of CFC-11	XXVII. Assuming Toxicity Rating of HCFC-123 is Adequate, But Significantly Worse Than That of CFC-11
Drug (Microcrystalline Suspension)	0.5	0.5
Excipient(s) (As Sorbitan Esters)	1.0	1.0
HCFC-123	13.5	
CFC-113		4.5
HCFC-141b		9.0
HFC-134a Propellant	75.0-85.0	75.0-85.0
HCFC-124 Propellant	10.0-none	10.0-none

TABLE 10. CALCULATED OZONE DEPLETION FROM MDID ITEMS (POUND EQUIVALENCE OF CFC-11)

Year	1988	1993
Present Formulas (No changes)	4.000 (MM lbs)	5.000 (MM lbs)
Formula XXV		
With 10% HCFC-124 (0.007)[a]	0.028 "	0.035 "
Without HCFC-124 (0.004)[a]	0.016 "	0.020 "
Formula XXVII		
With 10% HCFC-124 (0.042)[a]	0.168 "	0.210 "
Without HCFC-124 (0.039)[a]	0.156 "	0.195 "

[a] Formula's overall ozone depletion potential.

TABLE 11. PROPOSED FORMULA TRANSITION FOR SOLUBLE MDIDS

Ingredients	Present Formula, %	Proposed Formula, %
Soluble Drug	0.5	0.5
Sorbitan Trioleate	1.0	1.0
Ethanol - Absolute	8.5	8.5
CFC-114	36.0	
CFC-12	54.0	
HFC-134a		54.0
HCFC-124		36.0
Pressure (psig at 70°F, air free)	52.	66.
Stratospheric O_3 Depletion	0.88	0.01
Flammability		
Concentrate Solution	Flammable	Flammable
Total Product	Nonflammable	Nonflammable

Note: Ethanol (Absolute) has an Open Cup Flash Point of 65°F and is readily handled and filled in explosion-resistant settings.

Contraceptive Vaginal Foams

The present-day products of this sub-category are typified by the following formula:

XXXI.	Contraceptive (Spermicidal) Drug	10.5%
	Triethanolamine Myristate/Laurate	0.5%
	Deriphat 151C (Amphoteric or "Zwitterion" Surfactant)	4.0%
	Deionized Water	77.0%
	CFC-114	3.2%
	CFC-12	4.8%
	Pressure (psig at 70°F, air free)	47.
	Density (g/mL at 70°F)	1.031
	Flammability	Nonflammable

A reasonable replacement formula is as follows:

XXXII.	Above concentrate	92.0%
	Additional Deionized Water	4.0%
	Propellant A-46	4.0%
	16% Propane A-108	
	84% Isobutane A-31	
	Pressure (psig at 70°F, air-free)	46.
	Density (g/mL at 70°F)	0.983
	Flammability	Transient*

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*If the foam puff is touched with a lighted match, a blue flame will leap across the surface and immediately go out. The process can be repeated at will. Otherwise, the product is nonflammable because of the 91.0% water content.

If even this vestige of flammability cannot be tolerated, or if a more quick-breaking type of foam is wanted, at least 25% of the propellant must be converted to HFC-152a (CH_3-CHF_2), as in Formula XXXIII:

XXXIII.	Above concentrate	92.0%
	Additional Deionized Water	3.5%
	HFC-152a	1.5%
	Propellant A-60	3.0%
	33% Propane A-108	
	67% Isobutane A-31	
	Pressure (psig at 70°F, air-free)	61.
	Density (g/mL at 70°F)	0.987
	Flammability	None**

**By the usual test procedures. However, the propellants (individually or pre-blended) are flammable and must be dealt with under highly controlled conditions.

The FDA (Drug Division) has jurisdiction over this product via their NDA program. They may require the use of a nonflammable propellant.

Apart from nitrous oxide (N_2O), which would cause a meter-foam valve to deliver significantly more drug near the end of the can than at the beginning, the only nonflammable, non-CFC choice would be certain blends of HCFC-22 (at least 40%) and HCFC-142b. The formula is as follows:

XXXIV.	Above concentrate	92.0%
	Additional Deionized Water	1.5%
	HCFC-22	2.6%
	HCFC-142b	3.9%
	Pressure (psig at 70°F; air free)	64.
	Density (g/mL at 70°F)	1.013
	Flammability	None

NOTE: The pH value must not exceed 8.2 at 77°F, or the HCFC-22 will hydrolyse, reducing the pH, and forming chloride ion that may act to corrode the aluminum canister.

Various possibilities for reformulation also exist for the "future alternative" propellants, such as a blend of HFC-134a/HCFC-142b or HFC-134a/HCFC-124, but these may be 7 to 10 years away from commercialization.

Formula XXXII may be the best alternative, since hydrocarbon propellants are highly flammable and must be handled and filled in well-ventilated enclosures containing only explosion-proof equipment and outfitted with an appropriate electroprotective system for detection, alarm, and other automatic responses.

Mercaptan (Thiol) Warning Devices

Present formulations of this product are essentially like the following:

XXXV.	Ethyl Mercaptan (CH_3-CH_2-SH)	2.0%
	CFC-12	98.0%

This product is used rarely, but can be employed to detect methane and carbon monoxide gases in coal mines and to automatically release the stench to warn those unable to hear the audio-alarms. The released material must be nonflammable.

An alternative formula, using presently available propellants is as follows:

XXXVI.	Ethyl Mercaptan	2.21%
	HCFC-22	39.12%
	HCFC-142b	58.67%
	Pressure (psig at 70°F; air free)	64.5
	Density (g/mL at 70°F)	1.217
	Flammability:	None (but borderline)

Fillers who do not have suitable facilities for handling flammable propellants must purchase the HCFC-22/HCFC-142b (40:60) nonflammable blend.

Intruder Alarm Devices

Present formulations consist of the following:

XXXVII. 100.0% CFC-12

These 6 and 12 Av.oz. cans are used as home, car, and boat sensory alarm equipment to sound a high-intensity (90-110 decibel) horn if the system detects movement, selected sounds, or other occurrences. Since large amounts of propellant are emitted under conditions beyond the marketer's control, e.g., in computer rooms, near sparking equipment, etc., it is necessary to use a nonflammable composition or an electric alternative device.

Most of these dispensers use an internal dip tube to carry the liquified gas through the valve and into the expansion chamber of the horn, where it expands to the gaseous state. One mL of CFC-12 produces 256 mL of gas at 70°F and atmospheric pressure. Strong chilling of the chamber and icing of the humidity in the air may occur, but this has no effect on the horn properties. Nevertheless, to relieve such icing (but not the chilling), some formulas are revised to the following:

XXXVIII.	85.0%	CFC-12
	15.0%	Ethanol Absolute (or Methanol Absolute)

In such cases, 1 mL of product produces 236 mL of CFC-12 and alcohol vapor in use. The mixture is still nonflammable.

Conversion to non-CFC ingredients can be readily effected using the following composition:

XXXIX.	60.0%	HCFC-142b
	40.0%	HCFC-22

Pressure: 63 psig at 70°F (air free)
Pressure: 69 psig at 70°F (22"Hg° vacuum crimp)

Since this composition is just barely nonflammable, there is no latitude for adding (flammable) alcohols for de-icing purposes. Some conversions to 100% HCFC-22 in heavier cans have already taken place.

Also, unlike pure CFC-12, a distillation effect will accompany any additions of strongly chilled Formula XXXIX to an empty can. The preferential evaporation of nonflammable HCFC-22 will cause the residual liquid in the can to become technically flammable and lower in pressure. Although the flammability will be of small consequence unless the HCFC-22 sinks to about 32.0% or so, these effects do constitute a drawback. Any fillers using refrigeration-filling methods will have to change to pressure-filling techniques, including the drawing of a partial vacuum (22"Hg° minimum) in the can before introducing the liquid to avoid this effect. The density will be 15% lower than for CFC-12, but the gas volume per mL will be higher.

Flying Insect Sprays for Food-Handling Areas

The present exemption is for non meter-spray and non total-release spray pesticides in commercial food-handling areas.

A typical formulation for such a product would be as follows:

XL.		
	2.0%	Toxicants
	13.0%	Anhydrous Ethanol (As S.D. Ethanol 40-2; 200°)
	42.5%	CFC-11
	42.5%	CFC-12

For the following reasons, most of the original product volume has been replaced with water-based formulas when using hydrocarbon gases as the propellant:

- The spray cannot be ignited with a flame because of the presence of water;
- Food-handlers were using the CFC-type sprays for locker rooms, bathrooms, offices, and other areas in the establishment; and
- The factory cost of a 16 Av.oz. flying insect killer, using CFCs, was $0.42/can higher than the cost of the water-based, hydrocarbon product, not considering manufacturing losses, which would add $0.03 to $0.05/can. This would increase to about $1.00/can more (minimum) at wholesale prices.

A typical hydrocarbon product formula is as follows:

XLI.

2.0%	Toxicants
1.0%	Petroleum Distillates (Food Grade)
0.4%	Non-ionic Emulsifier (As Tween 80, by ICI America)
0.1%	Morpholine
0.1%	Sodium Benzoate (Food Grade)
64.4%	Deionized Water; USP
30.0%	Hydrocarbon Blend BIP-40 (Food Grade)
	18% Propane A-108
	33% Iso-butane A-31
	49% n-Butane A-17

Pressure: 47 psig at 70°F (21"Hg° vacuum crimp)
Delivery Rate: 0.62 g/sec at 70°F - initial
Density: 0.904 g/mL at 70°F
Flammability: None, by standard tests

NOTE: The hydrocarbon blend is extremely flammable, and special methods must be employed to handle and fill it safely.

If an anhydrous, nonflammable formulation is regarded as "essential," the following would suffice:

XLII.

2.0%	Toxicants
42.0%	HCFC-22
56.0%	HCFC-142b

Pressure: 69 psig at 70°F (with 22"Hg° vacuum crimp and gas purge)

Density: 1.213 g/mL at 70°F.

The cost, however, may preclude serious interest in this formulation.

Flying Insect Sprays for Aircraft

The present fumigation sprays for aircraft cabins are composed of the following:

XLIII.	1.0%	Pyrethrins/Cinerins (20% in Petroleum Distillates)
	1.0%	Piperonyl Butoxide - Technical
	49.0%	CFC-11
	49.0%	CFC-12

Other toxicant systems, such as 2.0% Sumethrin or 2% Resumethrin, are beginning to be used because of the high-cost and sporadic unavailability of Pyrethrin/Cinerin natural products. Products with the same formulation as Formula XL above are used in some areas.

The most reasonable alternative would be the following:

XLIV.	2.0%	Toxicants (As described just above)
	40.0%	HCFC-22
	58.0%	1,1,1-Trichloroethane - Inhibited (4).

Pressure: 68 psig at 70°F (with 22"Hg° vacuum crimp and gas purge)

Density: 1.270 g/mL at 70°F
Flammability: None

If the generally acceptable odor of 1,1,1,-trichloroethane-inhibited is too noticeable or disagreeable, the much more costly Formula XLII could be substituted.

Flying Insect Sprays for Tobacco Barns

As discussed in Section 3, these sprays consist entirely or almost entirely of 9-, 15- and 25-pound refillable cylinders containing 40 to 60% "Vapona" (organo-phosphate) insecticide and 60 to 40% CFC-12. These containers are not classified as "aerosols" by the aerosol industry. Nevertheless, it is appropriate to identify an acceptable alternative composition, such as the following:

XLV.	40 to 65%	Vapona™ Insecticide - Technical (95% min.)
	35 to 60%	HCFC-22

Pressure: About 75-100 psig at 70°F (air-free refill)
Density: About 3 to 7% lighter than the CFC-12 product

NOTE: HCFC-22 is a better dispersant than CFC-12, allowing the use of a somewhat higher level of Vapona (65% maximum). For such formulas, the standard amount of Vapona per cylinder can be used, and the same coverage per refill will apply.

This formula range is too high in pressure for "aerosol" containers, but they can be readily replaced (if used) with cylinder forms for this application.

Aircraft Maintenance and Operation Sprays

These sprays may be either nonflammable (CFC-based) or flammable (hydrocarbon-based) according to the conditions of use. For example, exterior touch-up paint could be flammable, typically using 29% Hydrocarbon Blend A-70 to A-85.

The nonflammable types include dusters, lubricants, and mold/mildewcides to be used in such areas as the cockpit, engine, and radio/radar area. Otherwise, air pockets within instruments and between close-packed equipment could be over-sprayed into the flammable range and such vapors be ignited by a spark source.

This means that, whenever possible, both the propellant and the total product should be nonflammable. Also, the use of solvents such as 1,1,1-trichloroethane-inhibited would often be contraindicated because of unwanted effects on the delicate electrical or electronic gear.

A typical alternative formulation could be patterned after Formula XII. A typical formulation for a mold/mildewcide would be as follows:

XLVI.	0.12%	o-Phenylphenol (As Dowicide 1 - Dow Chemical)
	0.38%	N-Morpholinium Soya Ethosulfates (G-271 - ICI)
	0.10%	Morpholine
	0.10%	Quaternary Ammonium Inhibitor (Q.A.I.-nitrite)
	24.30%	Deionized Water
	(Negligible Amount)	Acid form of Deriphat or Miranol Amphoteric "Zwitterion" Surfactants to pH = 8.0 - 8.2
	50.00%	Ethanol (Anhydrous) As SD Alcohol 40-2 200°
	25.00%	HCFC-22

NOTE: The water content may have to be reduced slightly, depending on pressure and phase compatibility. Pressure should not exceed 75 psig at 70°F.

The Set-A-Flash Open Cup flash point should not be below about 100°F for this formula because of the presence of water.

If even this minor degree of product flammability is of concern, a reformulation to use future alternative propellants such as the following will be necessary:

XLVII.	0.20%	BTC-2125M (80% A.I. quaternaries) Stepan Chem.
	0.10%	Quaternary Ammonium Inhibitor (Q.A.I.-nitrite)
	59.70%	HCFC-141b
	40.00%	HCFC-124

Pressure: 32 psig at 70°F (22"Hg° vacuum-crimp)
Density: About 1.28 g/mL at 70°F
Flammability: None

NOTE: The slight flammability of HCFC-141b is countered by HCFC-124.

Military Aerosols

As mentioned in Section 3, the bulk of these products are insecticides with the following formulation:

XLVIII.	2.0%	Toxicants
	49.0%	CFC-11
	49.0%	CFC-12

The military's rationale for requiring a nonflammable formulation is that they have no control over where these dispensers are used. For example, if a can were used to kill a roach in the cockpit of a fighter-jet, a sparking source could start a fire in a very confined, high-technology environment.

Partial resolution of this problem requires use of a nonflammable blend of presently available (ideally) HCFC propellants, e.g.:

XLII.	2.0%	Toxicants
	42.0%	CFC-11
	56.0%	HCFC-142b

For other "critical area," nonflammable military-use formulations, refer to the descriptions of the following formulas:

Formula XLVII: Mold/Mildewcide;
Formula XII: Lubricant; or
Formulas XX or XXI: Duster.

Diamond Grit Sprays

If this product type still survives in CFC-form, and if the amount of concentrate is 5% or less (flammable or nonflammable), or 20% or less (nonflammable), an alternative formulation to yield a nonflammable aerosol spray product could be the following:

IL.	2 - 20%	Concentrate Liquid
	98 - 80%	HCFC-Blend: 58% HCFC-142b 42% HCFC-22

CFC-115 for Aeration of Puffed Food Products--Certain Limitations Applied

This product use of CFC-115 has been discontinued because of a Department of Transportation (DOT) "Special Exemption" allowing the introduction of additional nitrous oxide (N_2O) propellant. No rekindling of interest in

CFC-115 for this use is anticipated, although no nonflammable replacement product is commercially available.

The following paragraphs cover excluded products (where the propellant is all or part of the "product."

Tire Inflators

Only one marketer is thought to be using CFCs for this product type. The approximate formula is as follows:

L.

- 45% Water-based Sealant Concentrate
- 55% CFC-Blend:
  - 40% CFC-114
  - 60% CFC-12

A number of deaths have occurred during the repair of tires containing an explosive mixture of air and hydrocarbon propellants, and insurance firms sometimes refuse to continue product liability coverage. The above formula has been one result of this. It is more costly and less effective than the standard 25 to 30% Hydrocarbon Blend A-46 formulas.

An alternative nonflammable formula would be as follows:

LI.

- 65% Water-based Sealant Concentrate
- 23% HCFC-142b
- 12% HCFC-22

Pressure: 56 psig at 70°F (air free)
Density: 1.087 g/mL at 70°F
Flammability: None--but borderline.

If a lower pressure is required, formulations would have to use future alternative HFC-134a in place of the HCFC-22.

Polyurethane Foams

The typically 30-35% CFC-12 used in these formulas as a nonflammable blowing agent consumes about 3.1 million pounds per year of CFC-12. The alternative agent must be nonflammable and chemically compatible with the foam. The following formulation is suggested:

LII.		
	66%	Polyurethane pre-polymer dispersion
	2%	Dimethyl Ether (DME) (Moisture Scavenger)
	17%	HCFC-142b
	15%	HCFC-22

Pressure: 48 psig at 70°F (air free)
Flammability: Combustible, because of the concentrate.
The HCFC blend is nonflammable.
The HCFC/DME blend is marginally nonflammable.

The pressure is about the same as is exerted by the CFC-12 in present formulas. The vapor volume would be about 26% greater. If less vapor volume is desired, 14% HCFC-142b and 12% HCFC-22 could be used. The DME ties up unwanted moisture in the aerosol can and prolongs the service life of the product.

Chewing Gum Removers

The current formula is 100% CFC-12, and the product is designed as a simple chiller for embrittlement of the gum, after which the frangible mass can be cracked apart and removed. No solvents can be used, or the chilling will be mitigated and softening of the gum surface may result.

The proposed alternative formula is as follows:

LIII.		
	44.0%	HCFC-22
	54.0%	HCFC-142b

Pressure: 70 psig at 70°F (22"Hg° v.c. plus purge)
Density: 1.24 g/mL at 70°F (CFC-12 is 1.34 g/mL 70°F)
Flammability: Nonflammable

Drain Openers

This product was developed by Glamorene, Inc. and marketed as "Drain Opener" by them. It was later sold to Lehn & Fink Products Group (Sterling Drug Co.) and then discontinued because of the high price and numerous in-use problems.

A formula like Formula No. LIII could be proposed for a non-CFC version, but the item is now dead, and no marketers seem to be interested in it as a future product possibility.

Chillers - Medical

These are presently CFC-12 or CFC-12/114 blends for topical application before localized incisions are made for removing warts, minor birthmarks, etc. Following is a suitable, currently available replacement formula:

LIV.	10.0%	Ethanol - Absolute (Pure Grain Spirits)
	50.0%	HCFC-142b
	40.0%	HCFC-22

Pressure: 67 psig at 70°F (22"Hg° vacuum crimp)
Density: 1.19 g/mL at 70°F
Flammability: Nonflammable propellant blend and nonflammable product by standard tests.
(The ethanol has a Set-a-Flash Closed Cup = 56°F.)

If desired, the ethanol can be removed from this formula. It is included as a pressure depressant, cost-reducer, and germicidal solvent. Medically-approved specially denatured ethanol grades, such as SDA-17, may be used in some cases.

Boat Horns

Formula IXL (described above) is suggested:

LV.	60.0%	HCFC-142b
	40.0%	HCFC-22

Non Electric/Electronic Dusters

Products in this class are used to blow dust off photograph records, tape decks, stylus tips, and so forth. If hydrocarbons were used, a flammable condition could result; e.g., 9.7 g of butanes will cause all the air in a 55-gallon drum to become flammable. Therefore, dusters should be nonflammable or essentially nonflammable in composition. The inclusion of solvents is contraindicated in general.

Formula XXXIX, discussed previously, is suggested:

XXXIX. 60.0% HCFC-142b
40.0% HCFC-22

Pressure: 63 psig at 70°F (air free)
Pressure: 69 psig at 70°F (22"Hg° vacuum crimp)

While these propellants are better solvents than CFC-12, their residence time on target surfaces would probably be too brief for any adverse effect.

Microscope Slide Cleaners and Related Products

When the target surface is not adversely affected by solvents that are more active than CFC-113, and when slightly slower evaporation rates can be tolerated, the following formula is recommended.

LVI. 72% 1,1,1-Trichloroethane - Inhibited (4)
28% HCFC-22

Pressure: Estimated as about 48 psig at 70°F
(with vacuum crimp)
Density: 1.302 g/mL at 70°F
Flammability: Nonflammable

When extreme purity and the evaporation rate and other properties indigenous to CFC-113 are required, the following formula can be used while research is conducted about the possibility of replacing the CFC-113 with HCFC-123, or with a blend of about 50% HCFC-123 and 50% HCFC-141b:

LVII.	73%	CFC-113
	27%	HCFC-22

The supplier of these future alternative products would have to be contacted about the possibility of making them available in highly purified forms.

Solvents - Medical

This is a minor use of CFC-113, for which it is uniquely qualified. The Dow-Corning Corporation, a maker of two such products, has examined the possibilities of using 1,1,1-trichloroethane (4) and methylene chloride and has pronounced them unsatisfactory.

Only two other possibilities can be offered:

Adhesive Spray:

LVIII.	3%	Silicone-based Adhesive
	80%	HCFC-141b (Marginally flammable; B.P. = 90°)
	17%	HCFC-22 (max.)
LIX.	3%	Silicone-based Adhesive
	41%	HCFC-141b (Marginally flammable; B.P. = 90°)
	40%	HCFC-123 (Nonflammable; B.P. = 82°F)
	16%	HCFC-22 (Nonflammable)

NOTES: The Adhesive is marketed as a 50% Active Ingredient dispersion in CFC-113. The supplier should reformulate the product to use perchloroethylene, 1,1,1-trichloroethane - inhibited, or HCFC-141b, in order of increasing volatility.

The preliminary results of toxicological tests now underway make the use of HCFC-123 uncertain.

There is concern about HCFC-141b because of its marginal flammability. This is probably sufficiently neutralized by the 17% HCFC-22 in Formula LVIII to eliminate any intrinsic problems. However, if nonflammability is an absolute requirement, the addition of the HCFC-123 in Formula LIX provides extra confidence, although testing would be required.

Adhesive Solvent Spray:

LX.	84%	HCFC-141b (Marginally flammable; B.P. = 90°)
	16%	HCFC-22 (Nonflammable) maximum
LXI.	42%	HCFC-141b
	42%	HCFC-123
	16%	HCFC-22

NOTES: As above, for HCFC components.

Contingency Products, Including Unauthorized Uses

Most of these will vanish as CFCs become progressively less available, beginning with the 15 to 25% effective reduction in production volume on July 1, 1989. (This effective reduction is due to the growth in CFC use since 1986, the baseline year for the Montreal Protocol-required CFC cutbacks.)

In general, CFC-12 can be replaced with 42% HCFC-22 and 58% HCFC-142b for those possible uses of CFC-12 not covered in this section.

SUMMARY

Of the 26 product categories examined in this section, most can be reformulated to eliminate or contain much lower concentrations of CFCs. The metered-dose inhalant drug (MDID) aerosols are the most difficult. To date, relatively little effort to reformulate products seems to have been expended by any of the CFC users, and this is particularly true of the "future alternatives," perhaps because of toxicological uncertainties and because the alternatives may not become commercially available for several years.

Pharmaceutical marketers (MDIDs, contraceptive foams, etc.) have expressed grave concern about dealing with the FDA Drug Division and reopening their NDA files, especially if numerous firms apply for amended NDAs concurrently, thus overloading the small FDA staff in this research area.

It is technically possible to reduce aerosol-related CFC uses to less than 25% of the present 25.5 million pound volume within five years with existing chemicals. Post-1994 reductions, however, depend on the toxicology of the alternatives and on what possible sacrifices in quality and convenience should be made to accommodate the need for maximum CFC reductions.

SECTION 5

PROCEDURES FOR AND COSTS OF SUBSTITUTING ALTERNATIVE FORMULATIONS FOR CFC AEROSOLS

INTRODUCTION

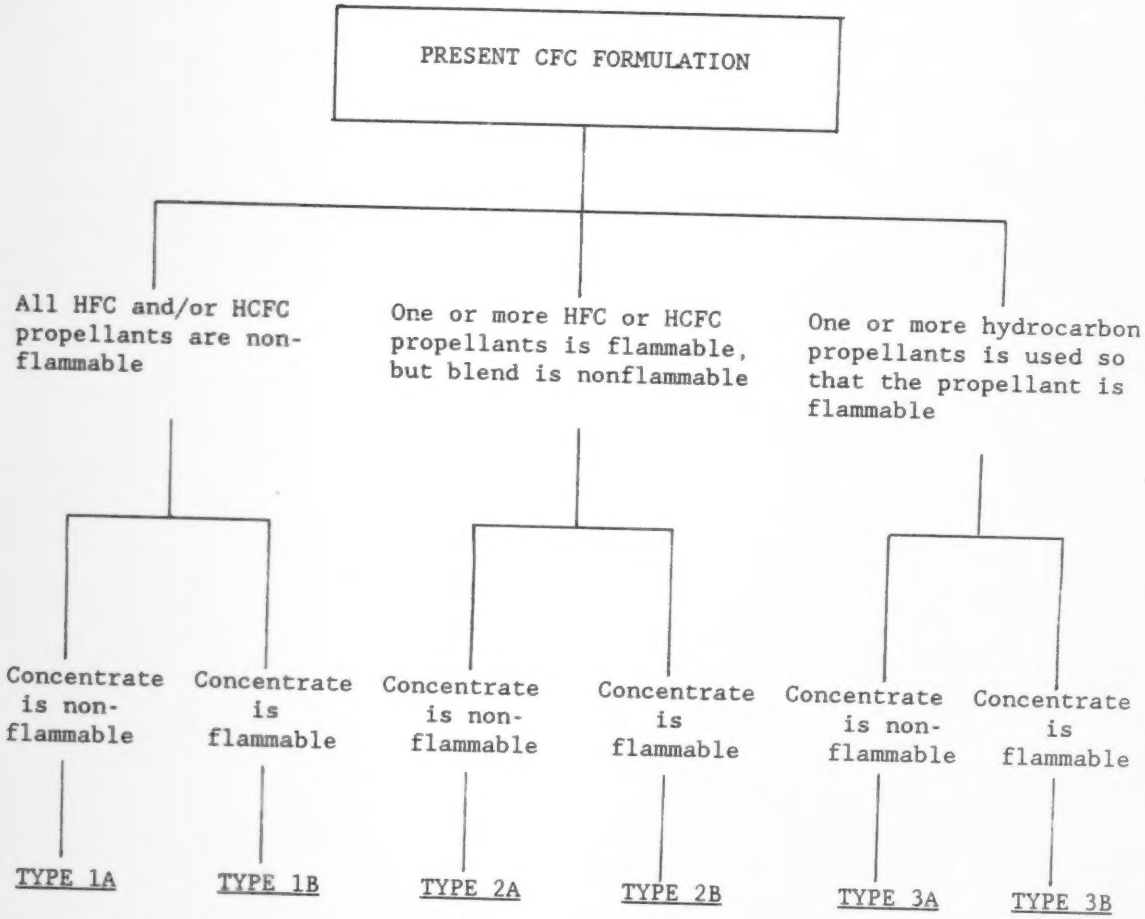
In Section 4, currently available substitutes for CFC aerosols and those that may be available in the future were considered for a total of 26 categories of aerosol products that currently use CFC propellants in whole or in part. Sixty-one formulations were described. For several products, more than one formula transition path was shown, but in each instance a preferred non-CFC formula was recommended.

When substituting alternative aerosol formulas for CFC-based aerosol products, one of the most important considerations is flammability. Depending on circumstances, one or more of three main formulation routes will be taken, as shown in Figure 1.

For firms producing CFC aerosols, the transition to non-CFC formulations will increase in difficulty and cost (and often decrease in acceptability) as the replacement formulas go from TYPE 1A to TYPE 3B (shown in Figure 1).

The costs of CFCs and current alternative propellants shown in Table 12 have been taken from price lists provided primarily by E.I. duPont de Nemours & Co. (Inc.), the only source for all of the gas-liquids. One price increase, effective on February 14, 1989, ranged from no increase for dimethyl ether to 15% increases for CFCs. The HCFC and HFC propellants were intermediate in price range.

Table 12 also includes estimates of the costs of these propellants in 1993 and 1994 and compares them with the present pricing schedule. These costs are speculative and assume a dramatic increase in the price of CFCs.


PRESENT CFC FORMULATION
All HFC and/or HCFC propellants are non-flammable
One or more HFC or HCFC propellants is flammable, but blend is nonflammable
One or more hydrocarbon propellants is used so that the propellant is flammable
Concentrate is non-flammable
Concentrate is flammable
Concentrate is non-flammable
Concentrate is flammable
Concentrate is non-flammable
Concentrate is flammable
TYPE 1A
TYPE 1B
TYPE 2A
TYPE 2B
TYPE 3A
TYPE 3B

NOTES: A propellant is here defined as "flammable" if it can produce a flammable composition (or range) in air.

A concentrate is defined as flammable if it exhibits a Set-A-Flash (Closed Cup) flash point of less than 100°F.

Figure 1. Aerosol Reformulation Options (1989 - 1993)

TABLE 12. CURRENT AND 1993/1994 PRICES FOR VARIOUS AEROSOL PROPELLANTS

Propellant	Current ($/lb)	Estimates for 1993/1994 ($/lb)
CFC-11	0.79	3.00
CFC-12	0.89	3.40
CFC-113	1.05	3.50
CFC-113 (Extreme Purity Grades)	1.40	4.00
CFC-114	1.23	4.0
CFC-115	NA[a]	NA[a]
Dimethyl Ether (DME or Dymel A)	0.38	0.55
HCFC-22	1.05	2.00
HFC-152a	1.60	3.40
HCFC-142b	2.40	3.25
HCFC-123	NA	4.00
HCFC-124	NA	3.70
HFC-134a	NA	4.40
HCFC-141b	NA	3.00
Carbon Dioxide	0.14	0.19
Hydrocarbons (Aerosol Grade)	0.18	0.23

Corollaries:

On a volume basis (gallon versus gallon), CFCs will cost about 42 times as much as hydrocarbons. On a weight basis, they will cost about 15 times as much.

On a volume basis, the HFC and HCFC alternatives will cost about 25 times as much as the hydrocarbons. On a weight basis, they will cost about 12 times as much.

On a volume basis, the future HFC and HCFC alternatives will cost about 38 times as much as the hydrocarbons. On a weight basis, they will cost about 16 times as much. Note that long-term prices are difficult to predict more accurately than within ± 25%.

On a volume basis, dimethyl ether will cost about 3.7 times as much as the hydrocarbons. On a weight basis, it will cost about 2.9 times as much.

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[a] Ton cylinders only.

COST OF CONVERTING FILLING LINES

Many of the current fillers and marketers of non-pharmaceutical CFC-type aerosol products are not equipped to handle flammable propellants. They could produce TYPE 1 products with no capitalization, and TYPE 2 products with minor capitalization, but for TYPE 3 products most would have to do one of the following:

- Commit very heavy capitalization, time, and educational resources to convert to hydrocarbon formulas and accept a statistical risk of fires and explosions; or
- Close down their facilities and go to a contract filler able to handle such products.

The cost to convert one medium-speed [80 to 160 cans per minute (cpm)] aerosol line to the filling of TYPE 3 products will vary with safety commitment levels but will range from $400,000 to $1,200,000. A probable average would be $900,000.

Table 5, which appears in Section 3 of this report, lists 34 filler and marketers handling TYPE 1 products. While these firms handle 90% of the non-pharmaceutical CFC business, it is estimated that an additional 30 to 40 firms, often termed "garage" operations, are also filling CFC aerosols. Smaller operators who elected to fill TYPE 3 products would be assuming a substantial risk. They would probably close down their operations or rely on a contract filler for continuing production.

It is estimated that about 12 of the larger CFC fillers would convert one line to filling TYPE 3 replacement formulas, because they currently have no such line and prefer to continue their in-house manufacturing activities for all of their products. Most of the remainder would convert to only TYPES 1 and 2 products or go to a contract filler.

Table 13 shows estimates of the total industry costs of in-house filler conversions from CFCs to the TYPES 1, 2, and 3 products defined in Figure 1.

The installation of a line able to handle TYPE 3 products would also permit the filler/marketer to fill other aerosol products that commonly use flammable products when such in-house filling business is out of reach because of the hazards involved.

The pharmaceutical industry currently has approximately 20 marketers that sell metered-dose inhalation drugs (MDID) and metered-dose contraceptive foams for human consumption under FDA exemptions. At least two U.S. contract fillers serve this group: Armstrong Laboratories, Inc. (West Roxbury, MA) and the 3M Health Care Specialties Division (St. Paul, MN). Approximately 10 production lines are currently engaged in the manufacture of these products.

The approximately 96 million units of microcrystalline MDIDs suspended in the propellant that are manufactured each year could be converted to a TYPE 1A formula (Formulas XXV and XXVII, as described in Section 4) without major cost. These two formulas are recommended.

When the MDID is dissolved in anhydrous ethanol (about 11 million units a year), a TYPE 1B formula (see Table 11) is recommended. Firms handling products in that subcategory are already manufacturing this formula, except for propellant selection; therefore, conversion costs should be minimal.

The last pharmaceutical category is the metered-dose contraceptive foam and its non-metered counterpart. The most reasonable conversion for this product is to a TYPE 3A formula, using hydrocarbon propellant blends. At least some of these products are being manufactured in-house by the marketers. They would have the option of spending about $900,000 per converted line, or going to contract fillers already set up to handle such products.

The above statements do not consider research (redevelopment) costs, regulatory costs (FDA-NDA), or marketing costs--only the manufacturing conversion outlays.

TABLE 13. COST ESTIMATES FOR PRESENT IN-HOUSE FILLER CONVERSIONS[a]

Conversion Mode	No. of Fillers	Lines	Costs ($)
CFC to TYPE 1	0	0	0
CFC to TYPE 2	12	13	4,000,000
CFC to TYPE 3	12	12	11,000,000
			$15,000,000

[a] Non-pharmaceutical firms only.

METHODS AND COSTS FOR DEVELOPING ALTERNATIVE FORMULATIONS FOR CFC AEROSOLS

The most appropriate way to discuss the cost-effectiveness of alternative approaches is on a product-by-product basis. The basis for the following discussion is 1) use of an average size container, and 2) the information in the "Product Volume of CFC Versions" column of Table 4 in Section 3. The calculated costs of interim formulations are based on an assumed dramatic increase in the price of CFCs.

Mold Release Agents

The per-can cost increase of converting:

3% Concentrate 57% CFC-11 40% CFC-12	to Formula V	3% Concentrate 65% HCFC-123 32% HCFC-22

in the average 1.11 lb dispenser can only be calculated in terms of 1993/1994 propellant prices, because HCFC-123 is not yet available and a price has not been established. Using parity for the concentrate and price estimates from Table 12 the following differential can be calculated:

$$\text{Diff.} = 1.11 \times 1.08 \times [(65\% \times \$4.00 + 32\% \times \$2.00) - (57\% \times \$3.00 + 40\% \times \$3.40)]$$

$$\text{Diff.} = 1.20\ [\$3.24 - \$3.07] = \$0.204 \text{ per can.}$$

Notes:

- Analysis assumes that the current can sizes can hold an extra 15 volume percent of product, since Formula V has a lower density than the present CFC formula (Formula I). Otherwise, a larger can or a smaller net weight will be required, adding to the cost per pound.
- The 1993/1994 prices are obviously speculative.

- The 1.08 factor takes into account an anticipated 8% propellant loss (during filling) for both formulas, which is about the industry average for these products.

Because it may be impractical to wait several years for the commercialization of the HCFC-123 used in Formula V, it is appropriate to look at the immediate conversion option, e.g.,:

Calculate the per-can cost increase of conversion from:

3% Concentrate
57% CFC-11
40% CFC-12

TYPE 1A

to

3% Concentrate
53% CFC-11
26% HCFC-142b
18% HCFC-22

TYPE 2A

Using costs effective on February 14, 1989, and parity for concentrate pricing:

The cost of CFC Formula I is:

1.11 x 1.08 [(57% x \$0.79) + (40% x \$0.89)]
= 1.20 [\$0.450 + \$0.189]
= \$0.967 for the CFCs in a 1.11 lb can, with loss.

The cost of CFC/HCFC Formula (not listed in Section 4) is:

1.11 x 1.08 [(53% x \$0.79) + (26% x \$2.40) + (18% x \$1.05)]
= 1.20 [\$0.419 + \$0.624 + \$0.189]
= \$1.478 for the CFC/HCFCs in a 1.11 lb can, with loss.

The cost difference would then be:

Diff. = \$1.478 - \$0.967 = \$0.511 per 1.11 lb average size can.

Notes:

- Analysis assumes the current can sizes can hold an extra 7 volume percent of product, since Formula V has a lower density than the present CFC formula (Formula I). Otherwise, a larger can or a smaller net weight will be required, adding to the cost per pound.
- The CFC content is immediately reduced from 97% to 53%; i.e., a 45% reduction. Ozone depletion is then reduced by about 43.6%.

Prices for Formulas III and IV are not calculated here because the use of methylene chloride may be difficult in light of its possible human toxicity, and because, according to industry sources, the relatively low volatility of 1,1,1-trichloroethane--inhibited will lead to an inferior product for many applications.

Summary

The cost of converting CFC Formula I to:

55% CFC/45% HCFC Formula IVa in 1989 will increase by about $0.511 per can;

100% HCFC Formula V in 1993/1994 will increase by about $0.204 per can; and

100% HCFC (+ chlorinateds) Formulas III or IV will change slightly in 1989.

The cost of a factory conversion from a TYPE 1A to a TYPE 2A product in 1989 is estimated to be $150,000 per moderate speed line. Note that the option of going to a contract filler is available. Several firms now use a contract filler, and a converted line could be also used for other products of TYPE 2A compositions.

Lubricants--For Electric/Electronic Equipment

Formula IX (see Section 4) will be taken as the standard, filled to 0.76 lb per can.

5% Specialty Lubricant Blend
65% CFC-113
30% CFC-12

The 1989 cost of the CFC components of this formula is as follows:

Cost = 0.76 x 1.08 [(65% x $1.40) + (30% x $0.89)]
= 0.821 [$0.91 + $0.267]
= $0.966 per can (with an 8% manufacturing loss of propellants; the 8% is an estimate of the propellant lost during filling).

In Section 4, formulas are presented for 1,1,1-trichloroethane and meter-spray options. If these are ruled out, we are left with a 1989 conversion to a CFC/HCFC formula, followed in 1993 or 1994 by conversion to a HCFC formula.

The proposed 1989 "partial conversion" formulation is the following:

5% Specialty Lubricant Blend
70% CFC-113
25% HCFC-22

The 1989 cost of the CFC/HCFC components is as follows:

Cost = 0.76 x 1.08 [(70% x $1.40) + (25% x $1.05)]
= 0.821 [$0.980 + $0.263]
= $1.020 per can (with an 8% manufacturing loss of propellants).

Conversion in 1989 from CFC Formula IX to the CFC/HCFC formula will cost:

$1.020/can - $0.966/can = $0.054/can

The reduction in CFC content is 26.3% and the reduction in ozone depletion is 24.2%.

A second stage of the reduction process could occur in 1993 or 1994, when HCFC-141b should become available. See Section 4, Formula XII:

5% Specialty Lubricant Blend
72% HCFC-141b
23% HCFC-22

Using 1993/1994 prices, the cost becomes the following:

Cost = 0.76 x 1.08 [(72% x $3.00) + (23% x $2.00)]
= 0.821 [$2.16 + $0.46]
= $2.15/can (with an 8% manufacturing loss of propellants).

The standard CFC (Formula IX) composition must be recalculated for 1993 and 1994 prices, from Table 12, to determine any differential.

Cost = 0.76 x 1.08 [(65% x $4.00) + (30% x $2.00)]
= 0.821 [$2.60 + $0.60]
= $2.63/can (with an 8% manufacturing loss of propellants).

Conversion in 1993 or 1994 from CFC (Formula IX) to HCFC (Formula XII) will save:

$2.63/can - $2.15/can = $0.48/can.

The 1993/1994 pricing structure for CFCs and HCFCs is very speculative. Cost increases or savings in conversion represent differentials and could be subject to considerable error.

Summary

The cost of converting from CFC Formula IX to:

> the 73.7% CFC/26.3% HCFC Formula will result in an increase (based on 1989 prices) of about $0.054/can; and
>
> the 100% HCFC Formula XII will result in a decrease (based on 1993/1994 prices) of about $0.48/can.

The 1,1,1-trichloroethane and meter-spray formulas are not considered here because they may have very limited applications. However, they are the least costly by far.

The cost of a factory conversion from TYPE 1A to a TYPE 1A (HCFC) formula in 1989 would be negligible.

Lubricants for Pharmaceutical Pill and Tablet Manufacture

The optimum immediate conversion possibility is for:

Formula XIII		Formula XIV
5% Concentrate		5% Concentrate
70% CFC-113 (Specially purified)	to	65% CFC-113 (Specially purified)
25% CFC-12		10% HCFC-142b
		20% HCFC-22
TYPE 1B		TYPE 2B

The average can size is 0.86 lb net weight. Costs are calculated as follows:

Formula XIII: Cost = 0.86 x 1.08 [(70% x $1.40) + (25% x $0.89)]
= 0.929 [$0.980 + $0.223]
= $1.118/can.

Formula XIV: Cost = 0.86 x 1.08 [(65% x $1.40) + (10% x $2.40) + (20% x $2.00)
= 0.929 [$0.910 + $0.240 + $0.400]
= $1.440/can.

The differential then becomes about $0.322/can. Reduction in CFCs would be 32%, and ozone depletion would be reduced by approximately 31%. The same can size could probably be used for equal weights of the alternative formula, since there is only about a 3% reduction in product volume. The manufacturing conversion cost would be negligible.

The preferred 1993/1994 alternative would be Formula XVI (see Section 4):

5.0% Concentrate
55.0% HCFC-141b
30.0% HCFC-124
10.0% HCFC-22

TYPE 2B

Costs are compared with Formula XIII (using 1993/1994 prices) as follows:

Formula XIII: Cost = 0.86 x 1.08 [70% x $4.00 + 25% x $3.40]
= 0.929 [$2.80 + $0.85]
= $3.39/can.

Formula XVI: $\text{Cost} = 0.86 \times 1.08\ [55\% \times \$3.00 + 30\% \times \$3.70 + 10\% \times \$2.00]$

$= 0.929\ [\$1.65 + \$0.20]$

$= \$2.75/\text{can}.$

The price decrease in going to the HCFC formula then becomes $0.64/can. This could be further decreased if a charge were made for extraordinary purification of the HCFC-141b volatile liquid component. The same size can could probably be used, with the same formula weight. The manufacturing conversion cost should be negligible in going from TYPE 1B to TYPE 2B.

The conversion of CFC Formula XIII to:

> the 68.4% CFC/31.6% HCFC Formula XIV will result in an increase (based on 1989 prices) of about $0.322 per average-size can for this product; and
>
> the 100% HCFC Formula XVI will result in a decrease (based on 1993/1994 prices) of about $0.64 per average-size can for this product. This decrease could dwindle, however, if the HCFC-141b requires special purification.

Contingency formulas, such as Formula XV, are discussed in Section 4 but are not priced here.

The conversion from a TYPE 1B to a TYPE 2B formulation should not have a significant impact in the manufacturing area.

Solvent-Cleaners, Dusters, and Coatings for Electric/Electronic Equipment

The standard formulation is the following:

Formula XVII

75% CFC-113
25% CFC-12

TYPE 1A

The standard can size is 0.51 lb.

The cost is calculated as follows:

Cost = 0.51 x 1.08 [(75% x \$1.40) + (25% x \$0.89)]
= 0.551 [\$1.05 + \$0.223]
= \$0.701/can.

The only immediately available conversion is to the following formulation:

Formula XIX

70% CFC-113
16% HCFC-142b
14% HCFC-22

TYPE 2A

and to closely related analogs, if a maximum amount of CFC-113 and CFC-12 is to be replaced.

The cost is calculated as follows:

$$\begin{aligned}\text{Cost} &= 0.51 \times 1.08\ [70\% \times \$1.40 + 16\% \times \$2.40 + 14\% \times \$1.05] \\ &= 0.551\ [\$0.98 + \$0.384 + \$0.147] \\ &= \$0.833/\text{can.}\end{aligned}$$

The present differential then becomes about $0.132/can. The reduction in CFCs would be 30%. The product density would decrease by about 11%, possibly requiring a larger can for the same fill weight, or else a reduction in fill weight. The manufacturing conversion cost would be negligible.

The ultimate conversion, to an entirely CFC-free formula, could take place around 1993 or 1994 when the "future alternatives" become commercially available. The preferred formulation is Formula XII (see Section 4), although others are given, according to the availability of HCFC-123 and the desire to use propane as a cost-cutting option. Following is a comparison of the 1993/1994 prices of Formulas XVII and XXI.

Formula XVII (1993/1994)	Formula XXI (1993/1994)
75% CFC-113	60% HCFC-141b
25% CFC-12	30% HCFC-124
	10% HCFC-22

As before, the 1993/1994 cost is calculated as follows:

$$\begin{aligned}\text{Cost} &= 0.51 \times 1.08\ [75\% \times \$4.00 + 25\% \times \$3.40] \\ &= 0.551\ [\$3.00 + \$0.85] \\ &= \$2.12/\text{can.}\end{aligned}$$

For Formula XXI the cost is calculated as follows:

$$\begin{aligned}\text{Cost} &= 0.51 \times 1.08\ [60\% \times \$3.00 + 30\% \times \$3.70 + 10\% \times \$2.00] \\ &= 0.551\ [\$1.80 + \$1.11 + \$0.20] \\ &= \$1.714\end{aligned}$$

The differential then becomes $0.41/can. The reduction in CFCs would be 100%, and the reduction in ozone depletion would be about 96%. The formula would be about 10 to 15% lower in density than the CFC counterpart, thus a slightly larger can, or slightly reduced-weight formula/package may be needed. Because the product is being converted from a TYPE 1A to another TYPE 1A product--assuming a three-component blend is prepared by the supplier and added to the can by the filler--, there would be a negligible effect on manufacturing conversion costs. It is not recommended that the slightly flammable HCFC-141b (B.P. = 90°F) be handled as a separate concentrate. Because of distillation effects in storage tanks, the filling of Formula XXI should be as follows:

- From a three-component blend in a bulk tank that is never allowed to sink below 35 volume percent full; or

- From a bulk tank of a two-component blend of HCFC-141b/124 in a ventilated, explosion-proof gas-house, followed by separate gassing of HCFC-22 into the cans.

The second option would force a conversion from TYPE 1A to TYPE 3A, which could cost up to about $400,000 to $1,200,000 per moderate-speed line. This is not recommended unless the filler already has such a TYPE 3 facility in place.

Summary

The 1989 price of converting Formula XVII to interim Formula XIX will result in an average increase of $0.132/can (CFC content will decrease by 30%).

The ultimate 1993/1994 price of converting to Formula XXI will result in a decrease of about $0.41 per can (CFC content will then be zero).

Metered Dose Oral and Nasal Inhalation Pharmaceutical Drug Products (MDIDs)

Formulations vary, but the "standard" formulation for the popular microcrystalline suspended (drug) solids type is as follows:

FORMULA MDID

2% Drug and Excipient Concentrate
24% CFC-11
24% CFC-114
50% CFC-12

The average package size is 0.033 lb.

The 1989 cost of the CFC ingredients is as follows:

$$\begin{aligned}\text{Cost} = {} & 0.033 \times 1.08\ [24\% \times \$0.79 + 24\% \times \$1.23 + 50\% \times \$0.89] \\ & 0.0356\ [\$0.190 + \$0.295 + \$0.445] \\ & \$0.0331/\text{canister}\end{aligned}$$

As discussed in considerable detail in Section 4, the industry has firmly rejected all currently available non-CFC propellants; therefore, there is no immediately available alternative whose price can be compared with that above.

The best future alternative formula for these products may be Formula XXV (the modification with 10% HCFC-124 propellant), which is as follows:

Formula XXV

2% Drug and Excipient Concentrate*
13% HCFC-123**
75% HFC-134a
10% HCFC-124

*Changed from 1.5% for a better comparison with Formula MDID, above.

**Based on this slurrying agent having a sufficiently low toxicity for the application. (Otherwise, use Formula XXVII, which has 4.5% CFC-113, but is similar in cost).

The 1993/1994 price for the CFC ingredients of the CFC Formula MDID is calculated as follows:

Cost = 0.033 x 1.08 [24% x \$3.00 + 24% x \$4.00 + 50% x \$3.40]
= 0.0356 [\$0.72 + \$0.96 + \$1.70]
= \$0.120/canister

The 1993/1994 cost of the HCFC and HFC ingredients in Formula XXV future replacement is calculated as follows:

Cost = 0.033 x 1.08 [13% x \$4.00 + 75% x \$4.40 + 10% x \$3.70]
= 0.0356 [\$0.52 + \$3.30 + \$0.37]
= \$0.149/canister

The cost increase for the HCFC replacement is then \$0.029 per canister.

For manufacturing purposes, Formula XXV is a TYPE 1A composition. The HCFC replacement formula is also a TYPE 1A, and all three HCFCs are nonflammable. Thus, manufacturing conversion costs should be minimal.

However, for these products, the cost of research, increased toxicology studies, dealing with the FDA (NDA-amendment), and additional quality control methods development would be considerable. They are estimated to be \$2,500,000 per product, for each of the approximately 21 products now on the U.S. market. When this is added to the manufacturing, marketing, and other costs, the industry total for converting is estimated to be about \$60,000,000, unless a more practical cooperative approach is used to qualify families of similar products.

Summary

No immediate or short-term conversion appears likely, especially in view of the lengthy product development, toxicological testing, and regulatory approval timeframe.

The 1993/1994 conversion will add a $0.029 cost increment to the CFC formulas. It will allow a 100% reduction in CFC content and a 99% reduction in ozone depletion potential.

About $60,000,000 in conversion costs is anticipated, industry wide.

The dissolved-drug forms of MDIDs have not been discussed (except briefly in Section 3), but their costs are comparable to those of the microcrystalline suspension forms. They represent less than 10% of the business volume and are provided by only two marketers, one of whom already has a microcrystalline suspension product in the line. An additional $3,900,000 conversion cost is estimated for these two marketers.

The total MDID conversion cost is therefore estimated to be about $64,000,000.

Contraceptive Vaginal Foams (Human Uses)

The current products average 0.16 lb net weight and contain about 3.2% CFC-114 and 4.8% CFC-12. A reasonable conversion would be to the hydrocarbon propellant form, using 4.00% Blend A-46, and 4.00% added water.

No rapid conversion is foreseen because of the usual 3- to 5-year FDA NDA time. Price comparisons based on 1993/1994 costs are therefore required.

Cost of CFC Formula XXXI:

Cost = 0.16 x 1.35 (loss) x [3.2% x $4.00 + 4.8% x $3.40]
= 0.216 [$0.128 + $0.154]
= $0.061/can

Cost of the Hydrocarbon A-46 Blend formula (Formula XXXII):

Cost = 0.16 x 1.25 (loss) x [4.0% x $0.23 + 4.0% x $0.005*]
= 0.200 [$0.0092 + $0.0002]
= $0.0019/can

* Cost of deionized water; U.S.P.

The conversion from a CFC to a hydrocarbon propellant would save $0.059/can in 1993/1994 prices.

This option, with the attendant cost savings, will appeal to those marketers who have their own line(s) already able to safely fill hydrocarbon propellants, or who have their product filled by contract fillers. Others will have to spend from $400,000 to $1,200,000 per moderate speed line, depending on the relative degree of safety desired or affordable.

For those marketers who wish to continue filling nonflammable propellants, or who are required by the FDA (Drug Division) to do so, the immediate alternative is the following:

Formula XXXIV

Concentrate	92.0%
Added DX-Water	1.5%
HCFC-142b	3.9%
HCFC-22	2.6%

TYPE 2A

The cost of this formula (minus the concentrate) is as follows:

$$\begin{aligned}\text{Cost} &= 0.16 \times 1.30 \text{ (loss) } [1.5\% \times \$0.005 + 3.9\% \times \$3.25 + \\ &\quad 2.6\% \times \$2.00] \\ &= 0.208\ [\$0.0001 + \$0.1268 + \$0.0520] \\ &= \$0.0372/\text{can}\end{aligned}$$

The differential, in 1993/1994 prices, between CFC Formula XXXI and HCFC Formula XXXIV is $0.024/can. Formula XXXIV is less expensive.

Summary

Because of the FDA (NDA) requirement, no immediate or short-term conversions are practical. Marketers will probably submit both hydrocarbon and HCFC formulas, and the FDA will decide which is safest for the user.

A conversion from CFC to hydrocarbon A-46 will save about $0.059/can in 1993/1994 prices.

A conversion of CFC to HCFC will save about $0.024/can in 1993/1994 prices.

Conversion to hydrocarbon A-46 will allow a 100% reduction in CFC content and a 100% reduction in ozone depletion from this product. Similarly, a conversion to HCFC will constitute a 100% reduction in CFC content and a 97% reduction in ozone depletion expected from the product.

Mercaptan (Thiol) Warning Devices

The standard formula can be immediately switched to an HCFC one, as follows:

Formula XXXV		Formula XXXVI
2.0% Ethyl Mercaptan		2.0% Ethyl Mercaptan*
98.0% CFC-12	to	39.2% HCFC-22
		58.8% HCFC-142b
TYPE 1B		TYPE 2B

*Changed from 2.21%. The 2.21% was designed to allow the same weight of ethyl mercaptan per unit volume of formula, i.e., the same size can. Thus, the amount of stenching agent per standard size can would stay constant. The change makes no real cost difference, yet allows both propellants to be calculated at the 98% level.

The cost difference can be developed as follows:

$$\begin{aligned}\text{Diff.} &= 0.95 \times 1.08\,[(39.2\% \times \$1.05 + 58.8\% \times \$2.40) - (98\% \times \$0.890] \\ &= 1.026\,[\$.4116 + \$1.4112 - \$.8722] \\ &= \$0.975/\text{can}.\end{aligned}$$

Thus, the replacement formula, which totally eliminates the CFC content, costs about $0.975/can more in 1989. Ozone depletion from this source is reduced by about 97%.

Fillers must handle the HCFCs as a pre-blend or install very costly facilities for handling HCFC-142b as a flammable gas.

Intruder Alarm Device Canisters

The standard formula can be compared with the immediately available alternative, as follows:

Formula XXXVII		Formula IXL
100% CFC-12	to	60% HCFC-142b 40% HCFC-22
TYPE 1		TYPE 2

The cost differential can be presented as follows:

Diff. = 0.47 x 1.08 [(60% x $2.40 + 40% x $1.05) - (100% x $0.89)]
= 0.5076 [$1.44 + $0.42 - $0.89]
= $0.492/can.

Thus, the HCFC replacement unit costs about $0.492/can more in 1989 and totally eliminates the CFC content. Ozone depletion from this source is reduced by 97%.

Fillers must handle the HCFCs as a nonflammable pre-blend, or else install very costly facilities for handling flammable HCFC-142b.

Flying Insect Sprays for Food-Handling Areas

The CFC-based product has been replaced with a hydrocarbon-propelled counterpart. Formulas can be compared as follows:

Formula XL		Formula XLI
15% Concentrate A 42.5% CFC-11 42.5% CFC-12	to	15% Concentrate B 55% Deionized Water 30% Hydrocarbon Blend BIP
TYPE 1B		TYPE 3A

Note: The cost of Concentrate A is very close to that of Concentrate B. They are considered the same.

The cost differential can be presented as follows:

Diff. = 0.76 x 1.08 [(42.5% x $0.79 + 42.5 x $0.89) - (55% x $0.005 +
30% x $0.180]

Diff. = 0.821 [$0.336 + $0.378 - $0.003 - $0.054]
= $0.539/can

Therefore, the marketer would save $0.539/can in factory cost by converting to the hydrocarbon version. The CFC would be eliminated and ozone reduction would be 0% of the CFC package.

A very costly HCFC alternate, Formula XLII, was described in Section 4 but would probably never be used.

Flying Insect Sprays for Aircraft

The compositions of the current CFC-based product and of a proposed HCFC-based alternative are as follows:

Formula XLIII		Formula XLIV
2% Toxicant Blend		2% Toxicant Blend
49% CFC-11	and	58% 1,1,1-Trichloroethane-Inhibited (4)
49% CFC-12		40% HCFC-22
TYPE 1A		TYPE 1A

The cost differential can be presented as follows:

Diff. = 0.48 x 1.08 [(49% x $0.79 + 49% x $0.89) - (58% x $0.36 +
40% x $1.05)]

Diff. = 0.5184 [$0.387 + $0.436 - $0.209 - $0.420]
= $0.100/can

Thus, the marketer would save $.100/can by changing to the HCFC-based formula. CFC usage would be eliminated and the ozone depletion would be reduced by about 97%.

A far more costly alternative using HCFC-22/HCFC-142b could be used if the 1,1,1-trichloroethane were not allowed for some reason.

Flying Insect Sprays for Tobacco Barns

This product probably does not exist in standard aerosol forms. For the 9 lb-, 15 lb-, and 25 lb-(net) cylinders now in use, CFC-12 could be replaced by HCFC-22 without fear of over-pressurization.

Considering that 40% HCFC will do the dispersant work of 50% CFC-12, a cost comparison can be made as follows:

Cost of 0.40 lb of HCFC-22 is 1.05 x $1.05 x 0.40 = $0.441
Cost of 0.50 lb of CFC-12 is 1.05 x $0.89 x 0.50 = $0.467

Differential: $0.026

This means that the cost of propellant gas per pound of insecticide is only $0.026 more for the alternative HCFC-22 formula.

Another approach is to consider the propellant cost in terms of each pound of Vapona dispersed. In this case, the cost of the HCFC-22 is less, since $0.735 of HCFC-22 sprays one pound of Vapona; whereas, $1.168 of CFC-12 is required to perform the same task.

Aircraft Maintenance and Operation Sprays

A number of different products fall into this (presently CFC) category. The lubricants, dusters, and insect sprays have already been reviewed above.

In Formula XLVI, 25% HCFC-22 replaces 20% CFC-12 in a hydro-alcoholic disinfectant/deodorant system for the control of mold and mildew. For a 14 Av.oz. average can the cost increase for the alternative formula calculates as follows:

$$\begin{aligned}\text{Diff.} &= 0.89 \times 1.08\ [25\% \times \$1.05 - 20\% \times \$0.89]\\ &= 0.959\ [\$0.2625 - \$0.178]\\ &= \$0.081/\text{can}\end{aligned}$$

A much higher-priced, essentially anhydrous HCFC-141b/HCFC-124 formulation is Formula XLVII, but its efficacy would probably vary with the available humidity in the air and, generally, Formula XLVI would be more effective.

Military Aerosols

The following analysis of Formula XLIII versus Formula XVIV applies to military flying insect sprays, as do the analyses of lubricants, dusters, etc.

The largest military purchases are for the 10-Av.oz. 2% toxicant, 98% CFC-12/11 insecticides. These can be compared with HCFC versions as follows:

Formula XLVIII		Formula XLII
2% Toxicants		2% Toxicants
49% CFC-11	to	42% HCFC-22
49% CFC-12		56% HCFC-142b
TYPE 1A		TYPE 2A

The 1989 cost differential can be determined as follows:

$$\begin{aligned}\text{Diff.} = 0.64 \times 1.08\ [&(49\% \times \$0.79 + 49\% \times \$0.89) - (42\% \times \$1.05 +\\ &56\% \times \$2.40)]\end{aligned}$$

$$= 0.691\ [\$0.387 + \$0.436 - \$0.441 - \$1.34]$$
$$= -\$0.662/\text{can}$$

Thus, a conversion to Formula XLII would cost $0.662 more per average-size can at the factory cost level. Formula XLII contains no CFCs and its ozone depletion potential would be 3% that of Formula XLVIII.

CFC-115 for Aeration of Food Products--Certain Limitations Applied

This market no longer exists, according to DuPont, the sole CFC-115 supplier. No future revival is anticipated.

EXCLUDED PRODUCTS

Tire Inflators

The prevalent formula types can be compared as follows:

Formula L		Formula LI(a)
45% Water-based Sealant		45% Water-based Sealant
22% CFC-114	to	30% Additional Water
33% CFC-12		25% Hydrocarbons A-46
TYPE 1A		TYPE 3A

Formula LI

45% Water-based Sealant
20% Additional Water
23% HCFC-142b
12% HCFC-22

TYPE 2A

Cost developments are as follows:

Formula L: Cost = 0.93 x 1.08 [22% x $1.23 + 33% x $0.89]
Cost = 1.004 [$0.271 + $0.205]
Cost = $0.478/can (for CFCs)

Formula LI(a): Cost = 0.93 x 1.08 [30% x $0.005 + 25% x $0.18]
Cost = 1.004 [$0.0015 + $0.0450]
Cost = $0.047/can (for extra water and A-46)

Formula LI: Cost = 0.93 x 1.08 [20% x $0.005 + 23% x $2.40 +
12% x $1.05]
Cost = 1.004 [$0.001 + $0.552 + $0.126]
Cost = $0.682/can (for extra water and HCFCs)

Differentials then become as follows:

Formula L to LI(a): a decrease of $0.431 per can (factory cost).

Formula L to LI: an increase of $0.204 per can (factory cost).

Diamond Grit Spray

Almost no substantive information on this product has been found. It is an exotic abrasive spray used for high-technology applications. Approximately 250,000 units a year are used.

Polyurethane Foams

Elimination of the present 32% CFC-12 formulation is suggested in favor of a 32% HCFC-142b/22 (17:15) blend.

Cost comparison is as follows:

Cost = 1.01 x 1.08 [(32% x $0.89) - (17% x $2.40 + 15% x $1.05)]
= 1.09 [$0.285 - $0.408 - $0.158]
= -$0.306/can (factory cost) differential

This will eliminate CFCs from this source and reduce ozone depletion by this product by 97%.

Chewing Gum Removers

The suggested transition is from a 100% CFC-12 formulation to a blend of 44% HCFC-22 and 56% HCFC-142b (see Formula LIII).

The cost comparison is as follows:

Diff. = 0.59 x 1.08 [100% x $0.89 - (44% x $1.05 + 56% x $2.40)]

Diff. = 0.6372 [$0.89 - $0.462 - $1.34] = $0.581/can = factory cost.

The switch to HCFCs will cost $0.581 more per average can at the factory and eliminate CFC emissions from this source. A 97% reduction in ozone depletion from these products will result. (As of July 1, 1989, DuPont and Allied Signal will no longer sell CFCs for this application.)

Drain Openers

This product is no longer on the market and will probably not be revived.

Chillers - Medical

The present and comparable future HCFC formulas can be compared as follows:

Formula LIV(a)		Formula LV
10% Ethanol - Anhydrous		10% Ethanol - Anhydrous
50% CFC-114	to	50% HCFC-142b
40% CFC-12		40% HCFC-22
TYPE 1B		TYPE 2B

Formula IV(a): Cost = 0.39 x 1.08 [50% x \$1.40 + 40% x \$0.89]
= 0.4212 [\$0.70 + \$0.356]
= \$0.445/can (for the CFCs) = factory cost

Formula IV: Cost = 0.39 x 1.08 [50% x \$2.40 + 40% x \$1.05]
= 0.4212 [\$1.20 + \$0.42]
= \$0.6823/can (for the HCFCs) = factory cost

The differential in price is \$0.237/can.

A transition to the HCFC formula would eliminate CFCs in this product and reduce ozone depletion from this source by 97%.

Non Electric/Electronic Dusters

A transition from 100% CFC-12 to a blend of 60% HCFC-142b and 40% HCFC-22 is suggested, as follows:

The cost differential should be as follows:

Diff. = 0.43 x 1.08 [(60% x \$2.40 + 40% x \$1.05) - (100% x \$0.89)]
Diff. = 0.4644 [\$1.440 + \$0.42 - \$0.890]
Diff. = \$0.450/can = factory cost

Microscope Slide Cleaners and Related Products

The following transition is suggested:

Formula LV(a)		Formula LVI
75% CFC-113		72% 1,1,1-Trichloroethane - Inhibited (4)
25% CFC-12	to	28% HCFC-22
TYPE 1A		TYPE 1A

Cost comparisons are as follows:

Diff. = 0.39 x 1.08 [75% x \$1.40 + 25% x \$0.89 - (72% x \$0.36 +
28% x \$1.05]

Diff. = 0.4212 [\$1.050 + \$0.223 - \$0.242 - \$0.294]

Diff. = \$0.310/can

This change would eliminate CFCs from this source and limit ozone depletion by these products to about 3% the current level.

No special manufacturing costs would be incurred. The HCFC formula would be about 3 to 4% lower in density, so changes in can size or net weight would probably not be required.

Solvents - Medical

The current formula cannot be replaced with any combinations of HCFCs or other formulations now available. In 1993/1994 a replacement formula could be provided. The two are compared, using 1993/1994 pricing, as follows:

Present Formula	Formula LIX
3% Concentrate	3% Concentrate
72% CFC-113 (Purified)	41% HCFC-141b
25% CFC-12	40% HCFC-123
	16% HCFC-22
TYPE 1A	TYPE 2A

Present Formula: Cost = 0.51 x 1.08 [72% x $4.00 + 25% x $3.40]
= 0.551 [$2.880 + $0.850]
= $2.055/can (factory cost) for CFCs

Formula LIX: Cost = 0.51 x 1.08 [41% x $3.00 + 40% x $4.00 +
16% x $2.00]
= 0.551 [$1.23 + $1.60 + $0.32]
= $1.736/can (factory cost)

The differential is thus $0.319/can. (The HCFC formula is less costly.)

A temporary reformulation can be created by replacing the CFC-12 with 18% HCFC-22.

The calculation is as follows:

Cost = 0.51 x 1.08 [82% x $1.40 + 18% x $1.05]
= 0.551 [$1.148 + $0.189]
= $0.7367/can

The differential then becomes $0.7367/can (CFC/HCFC) - $0.6770/can (CFC) = $0.0597/can.

Boat Horns

The present CFC-12 product costs are as follows:

$$\begin{aligned}\text{Cost} &= 0.77 \times 108\ [100\% \times \$0.89] \\ &= 0.8316 \times \$0.89 \\ &= \$0.7401/\text{can}\end{aligned}$$

A conversion to a 60% HCFC-142b + 40% HCFC-22 formula can be suggested, and the cost would then be:

$$\begin{aligned}\text{Cost} &= 0.77 \times 1.08\ [40\% \times \$1.05 + 60\% \times \$2.40] \\ &= 0.8316\ [\$0.420 + \$1.440] \\ &= \$1.547/\text{can}\end{aligned}$$

The differential between the two formulas is thus $0.807/can.

Contingency Products

This category includes miscellaneous uses too small to be recognized by CFC suppliers and the industry at large. It also includes unauthorized or illegal applications of CFC propellants to various aerosol products.

It doesn't include CFCs as a part of Halon fire extinguisher formulations or CFC aerosol-size refrigeration/air conditioner refill units, although these are surveyed as a part of the aerosol product volume per year; and it does not include the aerosol-size sterilants, based on about 10% ethylene oxide "tamed" in 90% CFC-12.

These products have a sales unit volume of about 410,000 cans. The can fill is estimated to consist of 0.50 lb CFC-based ingredients. The category is handled as if the products were medical solvents.

Cost - Present CFC cost: $0.6770/can

- Proposed 82% CFC-113 and 18% HCFC-22 formula cost: $0.7367/can

Cost differential: $0.0597/can.

Summary

Table 14 summarizes the short-term (1989) and long-term (1993/1994) price differentials of the CFC-based products described in detail in this section.

The double-dashes (--) in Table 14 signify that short-term, fully corrective measures can be taken, and that the longer-term availability of future "alternative" propellants is of no consequence. Triple dashes (---) signify that there is no definable short-term reformulation activity.

Where reasonable evidence exists that a product has been discontinued, zeros (0) in the unit volume column have been used to signify that there is no known or suspected production of the products. For the tire inflator, the cost of only one formula option has been calculated on a yearly basis: the one with a blended hydrocarbon (A-46) propellant. The alternative (nonflammable) version is too costly to consider.

In terms of manufacturing changeovers, such as the purchase of new tanks, new gas-houses, new monitoring equipment, employee education, etc., in-house fillers would spend an estimated total of $15,000,000 for non-pharmaceutical items.

Pharmaceutical and medical products are more difficult to revise, requiring more testing, more development, linkages with the FDA (NDA), in addition to manufacturing revisions. Total costs are estimated to be approximately $70,000,000, unevenly divided between marketers who contract-fill and those who self-fill. Twenty-two or twenty-three products are involved in the MDID area, for an increment of about $64,000,000. The rest are involved in the contraceptive foam area, for an increment of about $6,000,000.

TABLE 14. DIFFERENTIAL COSTS FOR SHORT-TERM AND LONG-TERM CONVERSIONS

Product Category	Unit Volume	Present CFC Cost Per Can ($)	Differential Per Can (Short-Term)($)	Differential Total (Short-Term)($)	Differential Per Can (Long-Term)($)
Mold Releases	1,320,000	0.967	0.511	674,500/yr	0.204 increase
Lubricant E/E	2,320,000	0.966	0.054	125,300	0.480 decrease
Lubricant Tab.	1,930,000	1.118	0.322	621,500	0.640 decrease
Solvent Cleaners, Dusters for E/E Equipment	10,900,000	0.701	0.132	1,438,800	0.410 decrease
MDID Inhalants	107,000,000	0.0331	---[a]	---	0.029 increase
Contraceptives	6,940,000	0.0181	---[a]	---	0.059 decrease[b]
Mercaptan Warn.	90,000	0.895	0.975	88,000	--
Intruder Alarm	1,210,000	0.452	0.492	595,300	--
Pesticide-Food	120,000	0.586	0.539	64,700	--
Pesticide-Aircraft	580,000	0.426	(0.100)	(58,000)	--
Pesticide-Tobacco Barns	60,000	0.467/lb	(0.026)/lb	(1,560)	--
Aircraft Maintenance	110,000 500,000	0.171 0.966	0.081 D/D[c] 0.054 Lubr.	8,100 27,000	-- --
Military Aerosols	1,960,000	0.568	0.662	1,298,000	--

(Continued)

TABLE 14. (Continued)

Product Category	Unit Volume	Present CFC Cost Per Can ($)	Differential Per Can (Short-Term)($)	Differential Total (Short-Term)($)	Differential Per Can (Long-Term)($)
Tire Inflators	1,650,000	0.478	(0.431) Hydr. 0.204 HCFC	(711,200) Hydr.	--
CFC-115 (Food)	0	-	---	---	--
Diamond Grit	250,000	-	---	---	--
Polyurethane Foam	9,170,000	0.310	0.306	2,806,000	--
Chewing Gum Remover	470,000	0.567	0.581	273,100	--
Drain Openers	0	-	---	---	--
Chillers - Medical	710,000	0.445	0.237	168,300	--
Non-E/E Dusters	860,000	0.413	0.450	387,000	--
Boat Horns, etc.	2,280,000	0.740	0.806	1,837,700	--
Microscope Slides	120,000	0.536	0.310	37,200	--
Solvents - Medical	1,090,000	0.677	0.060	650,700	0.319 decrease
Contingencies	410,000	0.677	0.060	246,000	--

[a] No 1989 conversion data can be provided for the Metered-Dose Inhalant Drug (MDID) or Human Contraceptive products, since any change requires FDA (NDA) approval, which may take 3 to 5 years from the time of application and submittal of the research data.

[b] This is based on using the recommended hydrocarbon propellant blend version. The FDA may or may not approve, because of the theoretical flammability.

[c] This is the mold/mildew disinfectant/deodorant; one of several products used by aircraft maintainers/operators. All the others have been grouped together under the heading of the very large lubricant area.

PROCEDURES FOR CHANGING FROM CFC TO ALTERNATIVE FORMULATIONS

The progression of events for changing formulas has been covered to some extent earlier in this and other sections, but it is more fully defined in the following paragraphs.

Research Phase

- Order new propellants, prepare and test samples.
- Develop analytical methods for quality assurance.
- Develop specifications for quality control.
- Develop can/valve compatibility with product, including weight loss data, temperature sensitivity, reductions in active ingredient assay, and any other changes.
- Provide Material Safety Data Sheets on chemicals, concentrate, and complete formula.

Manufacturing Preparations

- Test new product(s) in pilot facilities, if available.
- Order new equipment as necessary.
- Install and perform "shake-down" on new equipment.
- Obtain spare parts, manuals, and educate employees on the use of new equipment.
- Install explosion-resistant, highly-protected gas house if dealing with TYPE 2 or TYPE 3 formulations.

Sales and Marketing

- Prepare new cost information:
  - Factory cost data;
  - Selling cost data;
  - Manufacturing capitalization cost data;
  - Product re-development cost data; and
  - Regulatory liaison cost data.

- Prepare new product labels, literature, advertising, and timetables.

- Educate sales personnel as to advantages/disadvantages, costs, etc.

- Educate distributors.

- Prepare for orderly transition in the marketplace.

Production

- The complexity of reformulating will vary with the product, increasing with pharmaceutical drug types. The list of procedures is not meant to be complete, merely indicative.

SUMMARY

For a group of 26 product categories, the costs of short-term and/or long-term formula revisions have been calculated for current and optimum formulas, and later extended into the product cost increases or decreases shown in Table 14.

Data on product size, restrictions, estimates, etc. have been included, as well as predictions about the reduction of CFC content and the corresponding reduction of stratospheric ozone depletion by CFC source.

Complete elimination of CFCs is considered possible on a short-term basis for about 18 of the 26 product categories covered.

Data on the cost of manufacturing/research/quality control/regulatory activities have been presented. These amount to a total of about $15,000,000 for non-drug products and about $70,000,000 for drug products. Elements that could affect these numbers include the following:

- Marketer/fillers leaving the marketplace;
- Marketer/fillers going entirely to contract fillers;
- Possible cost savings from cooperation in the FDA/NDA process;
- Coalitions allowing several marketers to sell one FDA-approved formula/package; and
- Reduction in sales volume, so that smaller lines can be used.

Considerable formulation work and related activities are being conducted at this time, and the industry foresees a 25% reduction in the availability of CFCs by July 1, 1989, caused by implementation of the first phase of the Montreal Protocol.

SECTION 6

CONCLUSIONS

Sections 4 and 5 have examined reformulation possibilities for 26 categories of CFC aerosol products that have enjoyed exempted or excluded status relative to the CFC bans and limitations placed on the aerosol industry by the U.S. EPA and FDA in 1978. According to the particulars of their use, some of these products may be easily reformulated to exclude CFCs, and some may be difficult to reformulate. Several cannot be reformulated with existing alternative propellants, but must await the commercialization of the four "future alternative" propellants described in Sections 4 and 5. Others must not only wait for the development of these new propellants, but must then go through the 3- to 5-year NDA procedure imposed by the FDA.

AEROSOL USES FOR WHICH CFCS ARE DIFFICULT TO ELIMINATE (AND POSSIBLE INTERIM REFORMULATIONS)

The seven categories of aerosol uses from which CFCs are most difficult to eliminate are discussed in this section. However, partial or interim reformulations of some categories to decrease CFC use are also noted. Table 15 lists the categories and the U.S. consumption of CFCs from these categories in millions of pounds per year. The perceived need for CFCs in these products is based on the lack of available alternatives that can completely replace the CFCs at the present time; however, approximately 40 percent of the CFCs now used in exempted or excluded U.S. aerosol products can be immediately replaced. Further, alternative non-CFC formulations for the seven remaining CFC-dependent categories are judged technically feasible, pending the commercial availability of four "future" HCFCs and HFCs.

TABLE 15. AEROSOL USES FOR WHICH CFCs ARE DIFFICULT TO ELIMINATE

CFC Aerosol Product	U.S. Consumption of CFCs (MM lbs/yr)
Certain Mold Releases	1.5
Lubricants--for Electric/Electronic Applications	1.9
Lubricants--for Pharmaceutical Pill and Tablet Presses	1.0
Solvent cleaners, Dusters, etc. for Electronic/Electric Equipment	6.0
Metered-Dose Inhalant Drugs (MDID)	3.9
Contraceptives for Human Use	0.1
Solvents--Medical	0.6
TOTAL	15.0[a]

[a] This is (15.0/25.5) = 58.8% of the present usage level.

Mold Release Agents

Key necessary attributes are product purity, surface-spray characteristics, fast evaporation of all but the lubricant, and nonflammability.

The nonflammability attribute relates to safety during large-scale intermittent use in unprotected areas. Using additional product (as silicones) promotes surface-coating characteristics but adds more lubricant than needed, causing voiding problems in the molded pieces. The use of volatile solvents promotes surface-coating characteristics, but if they are flammable the total product will become flammable. The nonflammable solvents are restricted to methylene chloride and, possibly, 1,1,1-trichloroethane (4). The latter is not quite volatile enough for most uses, and traces contaminate molded plastics and elastomers because of its solvency. Methylene chloride is effective but is a possible mutagen. This solvent can remain dissolved to some degree in the deposited silicone film, and may then craze or matte the surface of molded parts. It is an extremely strong solvent. See formulations III and IV in Section 4.

The idea of using a meter-spray valve has been discussed with one mold release marketer; however, employees operating molding machines tend to grossly overuse these more costly products. Also, meter-spray valves do not work well with strong solvents.

One reformulation approach is to revise the formula to a combination CFC/HCFC type, thus reducing the CFC usage. For example, by using:

NOT:	BUT:
5% Silicone	5% Silicone
60% CFC-11	3% Isopar C (Heptanes)
35% CFC-12	22% HCFC-22
	70% CFC-11

CFC consumption could be decreased 26% (or 0.39 MM lbs per year).

CFC-11 will be a necessary ingredient of mold releasers until it can be replaced with a suitable nonflammable, very volatile liquid such as HCFC-123; B.P. = 82°F.

The production of molded plastic or elastomeric parts affects many industries, and certainly the electric and electronics industry. A machine, for example, may produce parts for a "sensitive" industry one day and a "nonsensitive" one the next. Providing different lubricants for each of the two would be hard or impossible. Electric and electronic parts must be perfectly molded and carry essentially no embedded or impregnated impurities.

Lubricants for Electric/Electronic Uses

Key necessary attributes are purity, surface-spray characteristics, intrinsic nonflammability and reasonably fast evaporation of all but the lubricant. CFC-113 is a preferred carrying agent. Unlike other chlorinated solvents, such as methylene chloride and 1,1,1-trichloroethane (4), it is not readily pyrolized to form corrosive agents that could change resistances and otherwise harm delicate equipment.

Meter-squirt applications might allow the inclusion of a higher percentage (to 70%) of lubricant per aerosol can, which may be a viable solution (with HCFC-22 propellant) for those applications that can be handled by means of an extension tube that fits into the aerosol valve button. Research needs to be conducted in this area. See the discussion of Formulas XI and X in Section 4.

As shown below, to reduce CFC consumption the CFC-12 can be replaced with an appropriate amount of HCFC-22:

5% Specialty Lubricant		5% Specialty Lubricant
65% CFC-113	TO:	73% CFC-113
35% CFC-12		22% HCFC-22

This will reduce the CFC content by 23% and consumption by 0.44 MM lbs per year. It may be possible to restrict the CFC product to electronic uses, and use non-CFC sprays for ordinary electric motors, crude relays, and other items that do not require a high degree of purity.

The ultimate elimination of CFC-113 from lubricants requiring it depends on the future availability of liquid HCFCs, such as HCFC-123 (nonflammable) and HCFC-141b (slightly flammable). The latter would have to be used with a sufficient amount of HCFC-22 to eliminate any intrinsic flammability of the complete product.

Another possible interim formulation is 5% Lubricant, 55% CFC-113, and 40% HCFC-142b. If this formula tests out successfully, the CFC content would be reduced by 42.1%, or 0.80 MM lbs/yr.

Lubricants for Pharmaceutical Pill and Tablet Manufacture

This product is similar to the previous one. It normally consists of 70% CFC-113 and 15% CFC-12. (See Formula XIII in Section 4.)

Key attributes are high-purity, nonflammability and surface-coating action; everything but the lubricant evaporates quickly from the dies.

A short-term, partial conversion can be made using the following formula:

Formula XIV (see Section 4)

5% Concentrate (FDA Approved)
65% CFC-113
10% HCFC-142b
20% HCFC-22

This change would effect a 32% reduction in CFC content, for a reduction in CFCs used of 0.32 MM lbs per year.

Complete conversion, which will require the use of future alternative HCFC-123 (nonflammable) and/or HCFC-141b (slightly flammable), is several years away.

No presently available nonflammable solvents can begin to compare with CFC-113 for this application. The use of others would cause die contamination and inclusion of extraneous materials in the tablets and pills. The high-efficiency transfer of lubricant to the press dies would be impaired as well.

Solvent-Cleaners, Dusters and Coatings for Electric/Electronic Equipment

Electronic circuitry chillers and related products should also be included in this extremely large category, which accounts for 23% of all CFC aerosol materials.

Again, CFC-113, while unique in its selective solvent action on greases and oils, does not harm plastic or elastomeric components of circuit boards and other sensitive equipment. It also has the appropriate levels of volatility and purity, and it is nonflammable.

Instead of the usual formulation, 75% CFC-113 and 25% CFC-12 (Formula XVII, Section 4), a short-term partial conversion to Formula XIX could be made:

70% CFC-113
16% HCFC-142b
14% HCFC-22

In this case, the CFC reduction is 30%, for a decrease in CFCs consumed of 1.8 MM lbs per year.

The final conversion will have to await the availability of HCFC-123 or of HCFC-141b. For strategic planning purposes, tests should be undertaken with samples of these HCFCs to see if they can replace CFC-113.

The chiller sub-category uses straight CFC-12, possibly amounting to 20% of the CFCs used in the main category. The utility of the nonflammable blend, HCFC-22/142b (40:60), should be tested to discover any problems, such as the minor flammability of a surface from which much of the HCFC-22 (nonflammable) has evaporated. No other options are currently available. A future option may be 20% HCFC-124 and 80% HFC-134a.

Metered-Dose Oral and Nasal Inhalation Pharmaceutical Products

This industry can make no progress toward reformulation with the presently available alternative propellants. Studies with laboratory samples of the potential new propellants should be encouraged, assuming the toxicological tests now being conducted ultimately permit the marketing of these propellants.

As soon as the toxicology tests are successfully completed, the industry can approach the FDA and begin the NDA process, which will take 3 to 5 years to complete. One problem is that several firms have NDAs that are 20 years old, and they no longer have a technical staff able to develop a new product that would meet all the requirements of a revised NDA.

This is a large industry, producing 107 million units of inhalants a year. Marketers claim their product saves thousands of lives a year and makes other lives more bearable. If the industry works now on future alternatives, instead of waiting until 1993 when the toxicological tests will probably be completed, the length of time needed for completing the NDA amendment process and going to market with a new product can be significantly shortened. The use of discontinued FC-C318 (DuPont) should also be considered.

Contraceptive Vaginal Foams (Humans)

Reformulation with hydrocarbon alternatives could be completed very quickly if permitted by the FDA, at which point the FDA NDA amendment process could commence.

It is difficult to assess the "essentiality" of foam insert contraceptives (spermicides). It may be a highly discretionary alternative to oral contraceptives or other methods, or it may be a physical or emotional necessity as viewed by some users.

In any event, the quantity of CFCs consumed in this product category is very low--below 0.1 MM lbs per year.

Solvents - Medical

These products are generally for gauge bandage adhesives and adhesive removers. The primary silicone-adhesive supplier (Dow-Corning) has stated that, for technical reasons, no solvent besides CFC-113 is acceptable. The reason(s) is unknown. They may not have considered the future CFC alternatives. It may be that a complete conversion will have to await the commercialization of HCFC-141b (with a similar solvency profile).

In the short term, since present formulas are propelled with either 25% CFC-12 or 5% CO_2 gas, it may be practical to gain a partial conversion by using 18% HCFC-22 as the propellant. A further reduction in CFC consumption may be made by using 11% CFC-142b with 14% HCFC-22.

In the latter case, formulas with 90 to 95% CFCs will be replaced with one containing 70% CFC-113. This will reduce the CFC content by about (22.5/92.5) = 24%, decreasing the quantity of CFCs required for this product.

POTENTIAL FOR REDUCTION OF CFC USE IN EXEMPTED AND EXCLUDED AEROSOLS

The CFC usage data presented in Table 15 can now be augmented to include CFC reductions that can be made in the short term by partially reformulating certain products. Table 16 shows possible reductions projected in CFC consumption in the U.S. These reductions are based on the following scenarios:

TABLE 16. PROJECTED ANNUAL CFC CONSUMPTION IN THE U.S. UNDER DIFFERENT SCENARIOS (MM LBS/YR)

CFC Products	Present Consumption	1990 Usage Scenario One	1990 Usage Scenario Two	1995 Usage Scenario Three	2000 Usage Scenario Four
Mold Releases	1.50	1.50	1.11	0.00	0.00
Lubricants-E/E	1.90	1.90	1.10	0.00	0.00
Lubricants-Tablets	1.00	1.00	0.68	0.00	0.00
Solvents-E/E	6.00	6.00	4.20	0.00	0.00
MDID Inhalants	3.90	4.00	4.00	5.25	0.50
Contraceptives	0.10	0.10	0.10	0.00	0.00
Solvents-Medical	0.60	0.60	0.46	0.00	0.00
ALL OTHERS	10.50	0.00	0.00	0.00	0.00
	25.50	15.11	11.65	5.25	0.50

Scenario One:

The use of CFC-11, CFC-12, CFC-113, CFC-114, and CFC-115 would no longer be permitted for aerosol products currently exempted or excluded from previous regulations restricting their use, with the following exceptions:

- Release agents for molds used in the production of plastic and elastomeric materials;
- Non-consumer articles used as cleaner-solvents, lubricants, or coatings for electrical or electronic equipment, including freezants;
- Lubricants for rotary tablet press-punch machines;
- Solvents for medical purposes; and
- Metered-dose inhalant drugs, contraceptive vaginal foams and other human drugs as authorized by the FDA.

Scenario Two:

In addition to the items in Scenario One, for the first four products listed above, the use of CFC-11, CFC-12, CFC-114, and CFC-115 will no longer be permitted, and the amount of CFC-113 in such products will be limited to 75% by weight of the total formulation.

Scenario Three:

All the above items are included in this scenario, and the "future alternative propellants" must be capable of replacing CFC-113 and CFC-11. Also, the FDA must approve hydrocarbon use in contraceptives.

Scenario Four:

Finally, in this scenario all the above items apply, as well as the following: 1) there must not be any unusual delays in FDA's NDA Amendment process, and 2) the respective industries must proceed with the necessary research without delay.

Table 17 compares the reductions in CFCs called for by the Montreal Protocol with the reductions shown in Table 16.

NEAR-TERM CFC REDUCTIONS

The nonflammable blend of HCFC-22/142b (40:60) has a pressure of about 63 psig at 70°F, air free, and thus compares with CFC-12, which has a pressure of 70.69 psig at 70°F, air free. Since the blend is not quite as high in pressure, yet has an average molecular weight (and thus dispersive volume) very close to that of CFC-12, it may be necessary to increase the volume by 5 to 10% above the amount of CFC-12 when replacing it. This is illustrated by the following reformulation:

MOLD RELEASE AGENTS

CFC Formula	HCFC/CFC Formula
3% Concentrate	3% Concentrate
57% CFC-11	54% CFC-11
40% CFC-12	28% HCFC-142b
	15% HCFC-22

This shows how conveniently the CFC-12 can be replaced with an existing propellant blend. Formulation chemists have additional latitude they can explore to develop certain advantages; e.g., see the following formulas:

TABLE 17. COMPARISON OF MONTREAL PROTOCOL AND QUICKEST REASONABLE CFC REDUCTION

Protocol	Amount of CFC Propellants Used for U.S. Aerosols			
	Early 1989	Late 1989	1994/1995	1999/2000
Montreal Protocol	25.5 MM lbs	20.4[a]	16.3[a]	10.2[a]
Scenarios 1-4 (see Table 16)	25.5 MM lbs	15.0 or 11.7[b]	5.25	0.0

[a] Based on the levels of CFCs consumed in 1986 by the U.S. aerosol industry. Actual reductions would consider total U.S. CFC consumption for all applications.

[b] To achieve a reduction in CFCs to 15.0 MM lbs, the CFCs in all nonessential aerosols must be replaced with HCFC, HFC, or hydrocarbon alternatives.

To achieve a reduction to 11.7 MM lbs, in addition to the above substitutions, as much HCFC or other propellants would have to be added to non-drug, "essential" products as possible, replacing all the CFC-12 content and perhaps minor amounts of CFC-113 or other CFCs. (This would be difficult to accomplish in less than 1 to 1-1/2 years.)

The cost of all reformulated products would increase, in many cases quite drastically, as shown in Section 5.

Formula A	Formula B
3% Concentrate	3% Concentrate
40% CFC-11	60% CFC-11
57% HCFC-142b	21% HCFC-142b
	16% HCFC-22
Compared with the HCFC/CFC formula, increases cost, lightens density, minimizes CFC-11.	Compared with the HCFC/CFC formula, reduces cost, increases density slightly, and increases CFC-11.

Extending the rationale behind Formula B would result in the following formulas:

Formula C	Formula E	Formula D
3% Concentrate	3% Concentrate	3% Concentrate
75% CFC-11	91% CFC-11	88% CFC-11
22% HCFC-22	6% CO_2	9% Propane A-108
Less costly	Still less costly	Least costly

The reduction of CFCs would not be as significant in these formulations.

A final approach, which may not be practical for every application, would use CFC-113 in place of the CFC-11, as shown below:

Formula F

3% Concentrate
35% CFC-113 (Purified)
62% HCFC-142b

Two reasons for using this approach are as follows:

- A heavy, surface-coating spray can be made using less CFC-113 than CFC-11; and
- CFC-113 is reported to be approximately 80% as damaging to the stratospheric ozone layer as CFC-11.

The CFC-113 is sufficient to quell any minor flammability of the CFC-142b during product use, making it nonflammable. Also, compared with the CFC Formula, the CFC content is reduced by (62/97) = 64%, and the ozone depletion potential is reduced by:

$$1 - \frac{0.80 \times 35\%}{1.00 \times 97\%} = 71.1\%$$

This is, however, an unusually costly formula, about $1.22/lb of CFC/HCFC higher than the CFC formula.

This exercise shows that CFC-12 can be replaced with the nonflammable blend of HCFC-22/142b (40:60) or with some other blend of these alternative propellants, depending on concentrate and use factors. It is also desirable to replace the CFC-11 with 10-20% less CFC-113 and gain the added ozone protection. The drug aerosols (inhalants and contraceptives) are overseen by the FDA (NDA) and cannot be reformulated in this fashion.

Studies that should be conducted before further restrictions on CFC aerosols are announced include the following:

1. Offering formulation/packaging advice to affected marketers and seeking their feedback on product performance, manufacture, and standards compliance. For example:

    a. Will a proposed product sound a boat horn loudly enough, long enough, and without icing up or other complications?

b. Can a proposed product be directly gassed with HCFC-22 in essentially all pressure fillers (gassers) without blow-by, vapor-locks, gasket deterioration effects, etc.?

c. Will the formulations be considered satisfactory while limited by the Department of Transportation (DOT) to pressures of 180 psig at 130°F?

d. If CFC-113, held in one bulk tank, and HCFC-22, held in another bulk tank, are pre-blended at the filling plant, then placed in a small (1,000 U.S. Gallon) run tank designed to supply the blend to the pressure-filler (gasser)--allowing the gasser to fill the can in a one-stage operation for CFC-113/HCFC-22 formulas--are any problems caused by distillation in the (variably filled) run tank, with air remaining in the can and contributing to pressure, etc.?

   Note: This filling option, which favors the larger filler, conserves CFC-113, compared with using 750-lb drums of that solvent. The bulk price is also more attractive than the drum price, though this is offset to some degree by a larger inventory.

2. Examining the availability of HCFC-142b (CH_3-$CClF_2$) in light of the potential for its greatly increased use. Currently, the sole U.S. manufacturer is Pennwalt Corporation, which uses a complex, somewhat antiquated synthesis that is reflected in the present $2.40/lb price. Allied-Signal Corporation has made this product in the past at their Baton Rouge, LA facility, but their equipment may not still be in place. DuPont feels HCFC-142b is a major solution to the CFC problem, has developed a much-improved manufacturing process, and promises to supply HCFC-142b at a lower cost.

LONGER-RANGE CFC REDUCTIONS

Longer-range CFC reductions will probably be associated with eliminating the use of CFC-113, as in the following:

- Elimination of CFCs (as CFC-113) from the still-permitted "essential-use," non-medical products; and
- Elimination of CFCs from metered-dose inhalant sprays, hair restorers, and contraceptive foam products which are under FDA control and the subject of NDAs.

Subject to laboratory confirmations and field testing, one or two of the "future alternative" propellants, namely HCFC-141b and HCFC-123, might be used to replace CFC-113. Because of the slight flammability of HCFC-141b, it may be necessary to blend it with nonflammable HCFC-123. The proportion of HCFC-123 required to produce nonflammability is not known.

Based on 1988 production figures, and conforming with the suggested rule earlier in this section, a projection of about 7.55 million pounds of CFC-113 a year must be considered. (Note: This is the ozone depletion equivalent of about 40.25 million pounds of 1,1,1-trichloroethane - inhibited, of which about 6,000 million pounds are said to be made annually.)

Replacement formulations have been suggested earlier in Section 4; in particular, Formulas XXV and XXVII for the microcrystalline suspension type metered-dose inhalant drugs. Little or no work toward commercializing these options has yet been done by the pharmaceutical industry--either in the U.S. or worldwide. They require three propellants not now in commercial production, although each is available from industry pilot plant production.

Industry spokesmen suggest they may have formulations available in two to three years, after which they could go to the FDA to begin the 3- to 5-year NDA process. By this time, the propellants will be commercially available. In summary, they are visualizing a commercialization date of 1996-1999.

One of the two "best formula" options, Formula XXVII, requires 4.5% CFC-113 as part of the slurrying agent for nonflammability. This would amount to a use-level of about 0.176 million pounds per year, based on present U.S. production volumes.

Formula XXVII could be a reserve option: if the toxicological results obtained for HCFC-123 preclude this propellant from being used in inhalant sprays, the alternative Formula XXVII would have to be considered. The other option would be to force the pharmaceutical industry to somehow cope with the challenge of slurrying and grinding their drug/excipient items with a liquid, flammable propellant before filling aerosol canisters with the mixture. The industry states that they do not possess this technology, although the possibility of cryogenic slurrying exists.

The other medical products, solution-type inhalants, the virucidal inhalant for bronchopneumonia victims, contraceptive foam, and hair restorer, make up approximately 10-12% of the CFCs used for medical purposes, or some 0.4 million pounds a year. This industry should be amenable to the commercialization date of 1996-1999 mentioned earlier for the microcrystalline suspension inhalant sprays.

SUMMARY

Several possible interim alternative formulations for the seven categories of CFC aerosols still considered "essential" have been discussed in detail. Elements of the proposed CFC reduction plan have also been discussed and compared with the Montreal Protocol for the years 1989-2000. Further recommended studies on aerosol formulations are also discussed.

A longer-term CFC reduction plan would first involve eliminating CFC-113 for all non-medical aerosol products (assuming "future alternatives" are useful) and would effect a reduction of 84.3%--from 25.5 million pounds a year of CFCs used to 4.0 million pounds a year. This could occur by 1993 or 1994.

The final phase would consist of eliminating CFCs from the "essential-use" medical aerosol products by between 1996 and 1999.

REFERENCES

1. 43 FR 11301: March 17, 1978.

2. 40 CFR Part 82, (30566-30602) August 12, 1988.

3. United Nations Environment Programme, Montreal Protocol on Substances that Deplete the Ozone Layer, Final Act, 1987.

4. 1,1,1-trichloroethane (methyl chloroform) is also an ozone-depleting substance, although it is not subject to the Montreal Protocol.

5. Dunn, D. P. "CFC Propellants Today," Part 1, Aerosol Age, July 1988.

6. The information in the "Notes" to Table 3 was provided by John J. Daly, Jr. of DuPont, February 1989.

7. Communication with Trevor Lloyd, McLaughlin-Gormley-King Co., February 1989.

8. Communication with Carl Olson, Technical Products Corp., February 1989.

9. This was the conclusion reached by the Scientific Working Group at the third session of the ad hoc Working Group of Legal and Technical Experts for the Preparation of a Protocol on CFCs to the Vienna Convention for the Protection of the Ozone Layer, Geneva, Switzerland, April 27, 1987 (UNEP/WG.172/CRP.9).

APPENDIX A

Additional Information on MDIDs

ADDENDUM

The addendum in the following pages provides selected information that may be of interest concerning meter-spray CFC-containing ethical drug aerosol products.

ALUPENT METERED DOSE INHALER (ORAL) Boehringer-Ingelheim Pharmaceuticals, Inc.

Adrenergic bronchodilator.

0.225 g Meta-proterenol Sulfate, USP in a 15 mL container

Package provides 300 inhalations of 0.65 mg per dose. Two to three doses = equivalent to one inhalation. Limit: 12 inhalations per day.

Excipient: Sorbitan Trioleate

AZMACORT INHALER (ORAL) William H. Rorer, Inc.

Anti-inflammatory Corticosteroid--for control of bronchial asthma.

0.060 g Triamcinolone Acetonide in a 20 g canister.

Package provides at least 240 inhalations of about 200 micrograms (mcg) per dose, of which 100 mcg are delivered from the unit--in vitro. (Above 240 inhalations, the amount delivered may be inconsistent.)

Formula: Microcrystalline suspension of drug in 1% ethanol, plus CFC-12. (Suggest a slurry of 23.08% drug in ethanol is prepared.)

Toxicology: Teratogenic to rats and rabbits, causing cleft palate and/or internal hydrocephaly and/or axial skeletal defects at low incidence. Typical findings for glucocorticoids in animals.

AEROBID INHALER SYSTEM (ORAL) Forest Pharmaceuticals, Inc.

Anti-inflammatory and anti-allergic corticosteroid--for bronchial asthma.

About 0.027 g Flunisolide in a 7 g canister.

Package provides 100 inhalations of about 250 mcg drug, of which total systemic availability is about 40%--at 2.0 mg per day. The 2.0 g/day level is the chronic adult maximum.

Formula: Microcrystalline suspension of Flunisolide hemihydrate, with sorbitan trioleate (dispersant) and CFC-11, CFC-12, and CFC-114.

Toxicology: Teratogenic to rats and rabbits at 40 mcg/kg/day to 200 mcg/kg/day, as are other corticosteroids. Also feto-toxic.

BECLOVENT ORAL INHALER (ORAL) Glaxo, Inc. (Research Triangle Park, NC)

A corticosteroid for control of bronchial asthma.

About 0.0084 g of Beclomethasone Dipropionate, USP in a 16.8 g canister.

Package provides at least 200 inhalations. For adults, the maximum daily intake should not exceed 20 inhalations.

Formula: Microcrystalline suspension of beclomethacone dipropionate-trichloromonofluoromethane clathrate in oleic acid and CFC-11 plus CFC-12.

Toxicology: Teratogenic and embryocidal in the mouse and rabbit (but not the rat) when applied at ten times the maximum human dose per kg; e.g., cleft palate and absence of tongue.

BECONASE NASAL INHALER (NASAL) Glaxo, Inc. (Research Triangle Park, NC)

Identical to Beclovent Oral Inhaler, except for nosepiece.

DECADRON PHOSPHATE RESPIHALER (ORAL) Merck, Sharp & Dohme Division

Adrenocorticosteroid--for treatment of bronchial asthma.

About 0.107 g of Dexamethasone Phosphate in a package provides about 170 inhalations in a 12.6 g canister.

Formula: Suspension of 0.5 - 4-micron particles of drug in 2% ethanol and fluorocarbons.

Toxicology:

DECADRON PHOSPHATE TURBINAIRE (NASAL) Merck, Sharp & Dohme Division

Identical to Decadron Phosphate Respihaler except for nosepiece.

MEDIHALER ERGOTAMINE (ORAL) Riker Laboratories, Inc.

Blood vessel constrictor (cranial)--for treatment of migraines and prodrome.

About 0.225 g of Ergotamine Tartrate in a 2.5 mL (about 3.45 g) vial.

P.36 mg drug per dose; thus, about 25 inhalations per vial.

Formula: Fine particle suspension of ergotamine tartrate, with sorbitan trioleate, CFC-11, CFC-12, and CFC-114. Drug is about 0.65% w/w.

Toxicology:

MEDIHALER-ISO (ORAL) Riker Laboratories, Inc.

Adrenergic bronchodilator--for control of bronchial asthma.

About 0.030 g of Isoproterenol Sulfate in a 15 mL (20.4 g) vial.

0.08 mg of drug per dose, and 300 doses per vial.

Formula: A fine suspension of about 0.15% w/w Isoproterenol Sulfate powder in sorbitan trioleate, CFC-11, CFC-12, and CFC-114.

Toxicology:

MEDIHALER-EPI (ORAL) Riker Laboratories, Inc.

Adrenergic bronchodilator--for temporary relief from bronchial asthma.

Epinephrine Bitartrate in a 15 mL (20.4 g) vial.

Each inhalation delivers 0.3 mg of the drug.

Formula: Epinephrine Bitartrate (suspension?) in cetylpyridinium chloride, sorbitan trioleate, CFC-11, CFC-12, and CFC-114.

DUO-MEDIHALER (ORAL)

Riker Laboratories, Inc.

Adrenergic bronchodilator--for control of bronchial asthma.

Isoproterenol HCl and Phenylephrine Bitartrate in 15 mL and 22.5 mL vials.

Each use releases 0.16 mg Isoproterenol HCl and 0.24 mg Phenylephrine Bitartrate in about 0.05 mL of inerts.

The 15 mL vial provides 300 inhalations.

Formula: Two drugs in micronized particles suspended in cetylpyridinium chloride, sorbitan trioleate, CFC-11, CFC-12, and CFC-114.

Toxicology:

OTRIVIN (NASAL)

Geigy Pharmaceuticals Division

Nasal decongestant.

Xylometazoline Hydrochloride, USP. (Meter-Spray; OTC.)

0.1% drug, in 15 mL aerosol bottle--plastic coated.

Formula:

Toxicology:

PROVENTIL (ORAL)

Schering Corporation

Beta-adrenergic bronchodilator--for reversible obstructive airway disease, and for prevention of exercise-induced bronchospasm.

Each use discharges 0.090 mg of Albuterol in about 0.126 g of inerts (c.a. 0.093 mL minimum). The package size is 17.0 g (12.5 mL).

The canister provides at least 200 doses.

Formula: 0.11% Albuterol, Oleic Acid, CFC-11, and CFC-12.

Toxicology: Teratogenic in mice at 14X the maximum human dose.

VANCENASE NASAL INHALER (NASAL)

Schering Corporation

A glucocorticosteroid--relief of symptoms of rhinitis and inflammations.

One inhalation provides 0.042 mg of the drug. Package size is 16.8 g.

8.4 mg of drug is present in the canister, equaling 0.05% (200 doses/can).

Formulation:	Microcrystalline suspension of beclomethasone Dipropionate trichloromonofluoromethane clathrate in oleic acid, CFC-11, and CFC-12.
Toxicology:	Teratogenic to laboratory animals.

VANCERIL INHALER (ORAL)

Schering Corporation

Same as the above, except for use of oral applicator.

TORNALATE (ORAL)

Winthrop-Breon Laboratories Div.
Sterling Drug, Inc.
Mfr'd by Sterling Pharmaceuticals, Inc.

Beta adrenergic bronchodilator--for bronchial asthma and bronchospasm.

0.8% Bitolterol Mesylate, 38% ethanol, Ascorbic Acid, Saccharin, Menthol, CFC-12, and CFC-114.

Bottle provides at least 300 doses of about 0.050 mL each, containing 0.37 mg of the drug.

Teratology:	Oral doses to rats and rabbits up to 557 times the maximum human inhalation dose, and in rats to 284 times that dose, produce no teratologic effects. (Some cleft palates were obtained through subcutaneous injection.)

VENTOLIN INHALER (ORAL)

Glaxo, Inc. (Research Triangle Park)

Selective Beta_2Adrenergic Bronchodilator--relief of bronchospasm.

About 0.118% Albuterol in a 17.0 g canister, providing over 200 inhalations of 90 mcg drug each.

Formulation: Drug (micronized suspension), in oleic acid, CFC-11, and CFC-12.

Toxicology: Teratogen, especially via subcutaneous routes.

BRETHAIRE (ORAL)

Geigy Pharmaceuticals Division

Beta-Adrenergic Bronchodilator--relief of bronchospasm.

Each 7.5 mL (10.5 g) canister provides about 300 x 0.25 mg inhalations.

Formulation:

	g/10.5 g Can	Percentage (w/w)
Terbutaline Sulfate	0.075	0.714
Sorbitan Trioleate	0.105	1.000
CFC-11	2.580	24.571
CFC-114	2.580	24.571
CFC-12	5.160	49.144

Toxicology: None.

SUMMARY

BRANDNAME	MARKETER	TYPE ACTION
Alupent Metered Dose Inhaler	Boehringer-Ingelheim	ORAL Bronchodilator
Aerobid Inhaler System	Forest Pharmaceutical	ORAL Corticosteroid
Azmacort Inhaler	William H. Rorer, Inc.	ORAL Corticosteroid
Beclovent Oral Inhaler	Glaxo, Inc.	ORAL Corticosteroid
Beconase Nasal Inhaler	Glaxo, Inc.	NASAL Corticosteroid
Brethaire	Geigy Pharmaceuticals	ORAL Bronchodilator
Decadron Phosphate Respihaler	Merck, Sharp & Dohme	ORAL Corticosteroid
Decadron Phosphate Turninaire	Merck, Sharp & Dohme	NASAL Corticosteroid
Duo-Medihaler	Riker Laboratories, Inc.	ORAL Bronchodilator
Medihaler - Epi	Riker Laboratories, Inc.	ORAL Bronchodilator
Medihaler - Iso	Riker Laboratories, Inc.	ORAL Bronchodilator
Medihaler Ergotamine	Riker Laboratories, Inc.	ORAL CONSTRICTOR
Proventil	Schering Corporation	ORAL Bronchodilator
Tornalate	Winthrop-Breon Labs	ORAL Bronchodilator
Vancenase Nasal Inhaler	Schering Corporation	NASAL Corticosteroid
Vanceril Inhaler	Schering Corporation	ORAL Corticosteroid
Ventolin Inhaler	Glaxo, Inc.	ORAL Bronchodilator

PRODUCT DISTRIBUTIONS

BRANDNAME OF INHALERS	NET WEIGHT (g)	BRONCHODILATOR ORAL	CORTICOSTEROID ORAL	CORTICOSTEROID NASAL	ERGOT. TARTR. ORAL
Alupent	21	XX			
Azmacort	20		XX		
Aerobid	7		XX		
Beclovent	17		XX		
Beconase	17			XX	
Decadron Ph. Resp.	13		XX		
Decadron Ph. Turb.	13			XX	
Brethaire	11	XX			
Medihaler - Epi	20	XX			
Medihaler - Iso	20	XX			
Medihaler - Ergot.	3.5				XX
Duo-Medihaler	20 & 30	XX			
Proventil	17	XX			
Tornalate	17	XX			
Vancenase	17			XX	
Vanceril	17		XX		
Ventolin	17	XX			
	16.0	8	5	3	1

APPENDIX B

Department of Transportation
Regulations for Compressed Gases
Title 49 Code of Federal Regulations
Part 173

Revised October 1, 1988

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(d) **Poisonous mixtures.** A mixture containing any poisonous material, Class A, or irritating material in such proportions that the mixture would be classed as poisonous under § 173.326(a) or § 173.381(a) must be shipped in packagings as authorized for these poisonous materials.

§ 173.306 Limited quantities of compressed gases. (a) Limited quantities of compressed gases for which exceptions are permitted as noted by reference to this section in § 172.101 of this subchapter are excepted from labeling (except when offered for transportation by air) and, unless required as a condition of the exception, specification packaging requirements of this subchapter when packed in accordance with the following paragraphs. In addition, shipments are not subject to Subpart F of Part 172 of this subchapter, to Part 174 of this subchapter except § 174.24 and to Part 177 of this subchapter except § 177.817.

(1) When in containers of not more than 4 fluid ounces capacity (7.22 cubic inches or less) except cigarette lighters. Special exceptions for shipment of certain compressed gases in the ORM–D class are provided in Subpart N of this part.

(2) When in metal containers filled with a material that is not classed as a hazardous material to not more than 90 percent of capacity at 70° F. then charged with nonflammable, nonliquefied gas. Each container must be tested to three times the pressure at 70° F. and, when refilled, be retested to three times the pressure of the gas at 70° F. Also, one of the following conditions must be met:

- (i) Container is not over 1 quart capacity and charged to not more than 170 psig at 70° F. and must be packed in a strong outside packaging, or
- (ii) Container is not over 30 gallons capacity and charged to not more than 75 psig at 70° F.

(3) When in a metal container charged with a solution of materials and compressed gas or gases which is nonpoisonous, provided all of the following conditions are met. Special exceptions for shipment of aerosols in the ORM–D class are provided in Subpart N of this part.

- (i) Capacity must not exceed 50 cubic inches (27.7 fluid ounces).
- (ii) Pressure in the container must not exceed 180 psig at 130° F. If the pressure exceeds 140 psig at 130° F., but does not exceed 160 psig at 130° F., a specification DOT 2P (§ 178.33 of this subchapter) inside metal container must be used; if the pressure exceeds 160 psig at 130° F., a specification DOT 2Q (§ 178.33a of this subchapter) inside metal container must be used. ~~In any event, the metal container must be capable of withstanding without bursting a pressure of one and one-half times the equilibrium pressure of the content at 130° F.~~
- (iii) Liquid content of the material and gas must not completely fill the container at 130° F.
- (iv) The container must be packed in strong outside packagings.
- (v) ~~Each completed container filled for shipment must have been heated until the pressure in the container is equivalent to the equilibrium pressure of the content at 130° F. (55° C.) without evidence of leakage, distortion, or other defect.~~
- (vi) Each outside packaging must be marked **"INSIDE CONTAINERS COMPLY WITH PRESCRIBED REGULATIONS."**

(b) **Exemptions for foodstuffs, soap, biologicals, electronic tubes, and audible fire alarm systems.** Limited quantities of compressed gases, (except poisonous gases as defined by § 173.326) for which exceptions are provided as indicated by reference to this section in § 172.101 of this subchapter, when in accordance with one of the following paragraphs are excepted from labeling (except when offered for transportation by air) and the specification packaging requirements of this subchapter. In addition, shipments are not subject to Subpart F of Part 172 of this subchapter, to Part 174 of this subchapter except § 174.24 and to Part 177 of this subchapter, except § 177.817. Special exceptions for shipment of certain compressed gases in the ORM–D class are provided in Subpart N of this part.

(1) Foodstuffs or soaps in a nonrefillable metal container not exceeding 50 cubic inches capacity (27.7 fluid ounces), with double or emulsified compressed gas, provided the pressure in the container does not exceed 140 p.s.i.g. at 130° F. The metal container must be capable of withstanding without bursting a pressure of one and one-half times the equilibrium pressure of the content at 130° F.

- (i) Containers must be packed in strong outside packagings.
- (ii) Liquid content of the material and the gas must not completely fill the container at 130° F.
- (iii) Each outside packaging must be marked **"INSIDE CONTAINERS COMPLY WITH PRESCRIBED REGULATIONS."**

(2) Cream in refillable metal receptacles with soluble or emulsified compressed gas. Containers must be of such design that they will hold pressure without permanent deformation up to 375 psig and must be equipped with a device designed so as to release pressure without bursting of the container or dangerous projection of its parts at higher pressures. This exception applies to shipments offered for transportation by refrigerated motor vehicles only.

(3) Nonrefillable metal containers charged with a solution containing biological products or a medical preparation which could be deteriorated by heat, and compressed gas or gases, which is nonpoisonous and nonflammable. The capacity of each container may not exceed 35 cubic inches (19.3 fluid ounces). The pressure in the container may not exceed 140 psig at 130° F., and the liquid content of the product and gas must not completely fill the containers at 130° F. One completed container out of each lot of 500 or less, filled for shipment, must be heated, until the pressure in the container is equivalent to equilibrium pressure of the content at 130° F. There must be no evidence of leakage, distortion, or other defect. Container must be packed in strong outside packagings.

(4) Electronic tubes, each having a volume of not more than 30 cubic inches and charged with gas to a pressure of not more than 35 psig and packed in strong outside packagings.

(5) Audible fire alarm systems powered by a compressed gas contained in an inside metal container when shipped under the following conditions:

- (i) Each inside container must have contents which are not flammable, poisonous, or corrosive as defined under this part;
- (ii) Each inside container may not have a capacity exceeding 35 cubic inches (19.3 fluid ounces);
- (iii) Each inside container may not have a pressure exceeding 70 psig at 70° F. and the liquid portion of the gas may not completely fill the inside container at 130° F., and
- (iv) Each nonrefillable inside container must be designed and fabricated with a burst pressure of not less than four times its charged pressure at 130° F. Each refillable inside container must be designed and fabricated with a burst pressure of not less than five times its charged pressure at 130° F.

(c) **Fire extinguishers.** Fire extinguishers charged with limited quantities of a compressed gas to not more than 240 psig at 70° F. are excepted from labeling (except when offered for transportation by air) and the specification packaging requirements of this subchapter when shipped under the following conditions. In addition, shipments are not subject to Subpart F of Part 172 of this subchapter, to Part 174 of this subchapter except § 174.24 and to Part 177 of this subchapter except § 177.817.

(1) Each fire extinguisher must be shipped as an inside packaging;

(2) Each fire extinguisher must have contents which are not flammable, poisonous, or corrosive as defined under this Part;

(3) Each fire extinguisher under stored pressure may not have an internal volume exceeding 1,100 cubic inches. For fire extinguishers not exceeding 35 cubic inches capacity, the liquid portion of the gas plus any additional liquid or solid must not completely fill the container at 130° F. Fire extinguishers exceeding 35 cubic inches capacity may not contain any liquefied compressed gas;

~~(4) Each fire extinguisher manufactured on and after January 1, 1976, must be designed and fabricated with a burst pressure of not less than six times its charged pressure at 70° F. when shipped.~~

(5) Each fire extinguisher must be tested, ~~without evidence of failure or damage, to at least three times its charged pressure at 70° F. but not less than 120 psig before initial shipment.~~ For any subsequent shipment, each fire extinguisher must be in compliance with the retest requirements of the Occupational Safety and Health Administration Regulations of the Department of Labor, 29 CFR 1910.157(d), and;

(6) Each fire extinguisher must be marked to indicate the year of the test (within 90 days of the actual date of the original test) and **"MEETS DOT REQUIREMENTS."** This marking will be considered a certification that the fire extinguisher was manufactured in accordance with the requirements of this section.

Note: The words "This extinguisher meets all requirements of 49 CFR 173.306" may be displayed in place of "MEETS DOT REQUIREMENTS" on extinguishers manufactured prior to January 1, 1976.

(7) When specification 2P or 2Q packagings are used, paragraphs (c)(4) through (6) of this section are not applicable provided each packaging meets the requirements of paragraph (a) of this section.

(d) **Truck bodies or trailers on flat cars; automobiles, motorcycles, tractors, or other self-propelled vehicles.** (1) Truck bodies or trailers with automatic heating or refrigerating equipment of the gas burning type may be shipped with fuel tanks filled and equipment operating or inoperative, when used for the transportation of other freight and loaded on flat cars as part of a joint rail-highway movement, provided the equipment and fuel supply are of a type examined by the Bureau of Explosives and approved by the Associate Director for OE. The heating or refrigerating equipment is considered as carriers equipment and is not subject to any other requirements of this subchapter.

(2) Automobiles, motorcycles, tractors, or other self-propelled vehicles equipped with liquefied petroleum gas or other compressed gas fuel tanks, provided such tanks are securely closed, are not subject to any other requirements for transportation by rail or highway. For transportation by water, see § 176.905 and 176.78(k) of this subchapter. For transportation by air, the fuel tank must be removed or emptied and securely closed.

(3) A cylinder which is a component part of a passenger restraint system and is installed in a motor vehicle, charged with nonliquefied, nonflammable compressed gas and having no more than two actuating

packed in strong outside packagings each having a net weight of 25 pounds or less.

(iii) In metal, rigid fiber, or composition cans or cartons or rigid plastic containers, each having a rated capacity of not over 20 pounds, overpacked in metal, wooden or fiberboard outside containers not exceeding 50 pounds net weight provided the solid mixture contains 10 percent or less corrosive material and the remainder of the mixture does not meet the definition of a hazardous material as defined in this subchapter.

(4) Flammable solids except for charcoal briquettes must be in inside containers each having a net weight of 1 pound or less, packed in strong outside packagings each having a net weight of 25 pounds or less. Charcoal briquettes may be shipped in packagings having a net weight of 65 pounds or less.

(5) Oxiders must be in inside containers each having a rated capacity of 1 pint or less for liquids or a net weight of 1 pound or less for solids, packed in strong outside packaging each having a net weight of 25 pounds or less.

(6) Organic peroxides must be:

(i) In inside containers which must be securely packed and cushioned with noncombustible cushioning material in strong outside packagings containing not over 1 pint or 1 pound net quantity of the materials. Cushioning is not required when the liquid is contained in strong, securely closed, plastic packagings, not over 1 ounce capacity each, properly packed to prevent leakage or breakage.

(ii) In strong outside packagings of 24 or less inside fiberboard containers, each having 70 or less securely closed tubes having a maximum fluid capacity of ⅙-ounce each and securely packed in noncombustible cushioning material. Each fiberboard container may not contain more than 1 pint of liquid.

(7) Poison B liquids or solids must be in inside containers, each having a rated capacity of 8 ounces or less by volume for liquids or of 8-ounces or less net weight for solids packed in strong outside packagings.

(8) Compressed gases must be:

(i) In inside containers, each having a water capacity of 4-fluid ounces or less (7.22 cubic inches or less), packed in strong outside packagings.

(ii) In inside metal container charged with a solution of materials and compressed gas or gases which is non-poisonous, meeting all of the following:

(A) Capacity may not exceed 50 cubic inches (27.7 fluid ounces);

(B) Pressure in the container may not exceed 180 p.s.i.g. at 130° F. (55° C.). If the pressure exceeds 140 p.s.i.g. at 130° F., (55° C.) but does not exceed 160 p.s.i.g. at 130° F., (55° C.) a specification DOT 2P (§178.33 of this subchapter) inside metal container must be used; if the pressure exceeds 160 p.s.i.g. at 130° F., (55° C.), a specification DOT 2Q (§178.33a of this subchapter) inside metal container must be used. In any event the metal container must be capable of withstanding, without bursting, a pressure of one and one-half times the equilibrium pressure of the contents at 130° F. (55° C.);

(C) Liquid content of the material and gas not completely fill the container at 130° F. (55° C.);

(D) The containers must be packed in strong outside packagings; and

(E) Each completed container filled for shipment must have been heated until the pressure in the container is equivalent to the equilibrium pressure of the content at 130° F. (55° C) without evidence of leakage, distortion, or other defect.

(iii) In a non-refillable inside metal container of 50 cubic-inch capacity or less (27.7 fluid ounces), with foodstuffs or soaps and with soluble or emulsified compressed gas, provided the pressure in the container does not exceed 140 p.s.i.g. at 130° F. (55° C.). The metal container must be capable of withstanding, without bursting, a pressure of one and one-half times the equilibrium pressure of the contents at 130° F. (55° C.) and must comply with the following provisions:

(A) Containers must be packed in strong outside packagings, and

(B) Liquid content of the material and gas may not completely fill the container at 130° F. (55° C.).

(iv) In refillable inside metal containers with cream and soluble or emulsified compressed gas packed in strong outside packagings. Containers must be of such design that they will hold pressure without permanent deformation up to 375 p.s.i.g. and must be equipped with a device designed so as to release pressure without bursting of the container or dangerous projection of its parts at higher pressures.

(v) In non-refillable inside metal containers charged with a solution, containing biological products or a medical preparation which could be deteriorated by heat, and compressed gas or gasses which is nonpoisonous and nonflammable. The capacity of each container may not exceed 35 cubic inches (19.3 fluid ounces). The pressure in the container may not exceed 140 p.s.i.g. at 130° F. (55° C.), and the liquid content of the product and gas may not completely fill the container at 130° F. (55° C.). One completed container out of each lot of 500 or less; filled for shipment, must be heated, until the pressure in the container is equivalent to the equilibrium pressure of the content at 130° F. (55° C.). There may not be any evidence of leakage, distortion, or other defect. Container must be packed in strong outside packagings.

(vi) In electronic tubes, each having a volume of not more than 30 cubic inches and charged with gas to a pressure of not more than 35 p.s.i.g. and packed in strong outside packagings.

(vii) In an inside metal container as a component of an audible fire alarm system powered by a compressed gas meeting the following provisions:

(A) Each inside container must have contents which are not flammable, poisonous, or corrosive as defined under this Part;

(B) Each inside container may not have a capacity exceeding 35 cubic inches (19.3 fluid ounces);

(C) Each inside container may not have a pressure exceeding 70 p.s.i.g. at 70° F. (21° C.) and the liquid portion of the gas may not completely fill the inside container at 130° F. (55° C.);

(D) Each inside container must be desinged and fabricated with a burst pressure of not less than five times its charged pressure or more at 130° F. (55° C.); and

(E) Each fire alarm system must be packed in a strong outside packaging.

SUBPART O

OTHER REGULATED MATERIAL; ORM-E.

§173.1300 Hazardous waste, liquid or solid, n.o.s.; hazardous substance, liquid or solid, n.o.s.

Hazardous waste, liquid or solid, n.o.s., or Hazardous substance, liquid or solid, n.o.s., may not be offered for transportation unless packaged in accordance with §173.510.

APPENDIX A—METHOD OF TESTING CORROSION TO SKIN

1. Corrosion to the skin is measured by patch-test technique on the intact skin of the albino rabbit, clipped free of hair. A minimum of six subjects are to be used in this test.

2. Introduce under a square cloth patch, such as surgical gauze measuring not less than 1 inch by 1 inch and two single layers thick, 0.5 milliliter (in the case of liquids) or 0.5 gram (in the case of solids and semisolids) of the substance to be tested.

3. Immobilize the animals with patches secured in place by adhesive tape.

4. Wrap the entire trunk of each animal with an impervious material, such as rubberized cloth, for the 4 hour period of exposure. This material is to aid in maintaining the test patches in position and retards the evaporation of volatile substances. It is not applied for the purpose of occlusion.

5. After 4 hours of exposure, the patches are to be removed and the resulting reactions are to be evaluated for corrosion.

6. Following the initial reading, all test sites are washed with an appropriate solvent to prevent further exposure.

7. Readings are again to be made at least at the end of a total of 48 hours (44 hours after the first reading).

8. Corrosion will be considered to have resulted if the substance in contact with the rabbit skin has caused destruction or irreversible alteration of the tissue. Tissue destruction is considered to have occurred if, at any of the readings, there is ulceration or necrosis. Tissue destruction does not include merely sloughing of the epidermis, or erythema, edema, or fissuring.

APPENDIX C
METRIC (SI) CONVERSION FACTORS

Quantity	To Convert Form	To	Multiply By
Length:	in	cm	2.54
	ft	m	0.3048
Area:	in^2	cm^2	6.4516
	ft^2	m^2	0.0929
Volume:	in^3	cm^3	16.39
	ft^3	m^3	0.0283
	gal	m^3	0.0038
Mass (weight):	lb	kg	0.4536
	oz	kg	0.0283
	short ton (ton)	Mg	0.9072
	short ton (ton)	metric ton (t)	0.9072
Pressure:	atm	kPa	101.3
	mm Hg	kPa	0.133
	psig	kPa	6.895
	psig	kPa*	((psig)+14.696)x(6.895)
Temperature:	°F	°C*	(5/9)x(°F-32)
	°C	K*	°C+273.15
Caloric Value:	Btu/lb	kJ/kg	2.326
Enthalpy:	Btu/lbmol	kJ/kgmol	2.326
	kcal/gmol	kJ/kgmol	4.184
Specific-Heat Capacity:	Btu/lb-°F	kJ/kg-°C	4.1868
Density:	lb/ft^3	kg/m^3	16.02
	lb/gal	kg/m^3	119.8
Concentration:	oz/gal	kg/m^3	
	quarts/gal	cm^3/m^3	25.000
Flowrate:	gal/min	m^3/min	0.0038
	gal/day	m^3/day	0.0038
	ft^3/min	m^3/min	0.0283
Velocity:	ft/min	m/min	0.3048
Viscosity:	centipoise (CP)	Pa-s (kg/m-s)	0.001

*Calculate as indicated